

## **Title 64 Series 23**

Department of Health and Human Resources

Bureau for Public Health

### **RADIOLOGICAL HEALTH RULES**

#### **Summary of Public Comments:**

The Radiological Health regulations, 64CSR23, addresses the use of all sources of radiation in West Virginia that are not regulated by the Nuclear Regulatory Commission (NRC) and include radiation producing equipment used in the medical, veterinary, and dental fields as well as many industrial and public safety uses.

#### **Response to General Comments:**

The health consequences of radiation exposure are well documented, particularly regarding cancer. The Bureau for Public Health (the "Bureau") must protect public health by ensuring that radiation exposure to humans are minimized. Radiation is necessarily used in medical and industrial settings. However, with every exposure to radiation over the course of a person's lifetime, the risk of cancer increases. Controls placed on the use of radiation and the handling of radioactive materials minimizes the risk to public health. Ensuring that radioactive materials are properly handled and disposed of lessens the need for costly of environmental remediation.

The Bureau's radiological health rule is modeled on the regulations suggested by the Conference of Radiation Control Program Directors (CRCPD). The CRCPD is a cadre of radiation experts from around the country who work collaboratively to ensure radiation is used as safely as possible and unnecessary exposures are minimized. The CRCPD has drafted model state regulations aimed at bringing uniformity to radiation safety efforts across the United States.

The comments received are primarily directed to changes to section 16 of the rule relating to the control of radiation containing materials from naturally occurring sources resulting from fracking practices by the oil and gas industry. The naturally occurring radioactive materials that undergo processing and results in higher concentrations of radiation are called TENORM (technologically enhanced naturally occurring radioactive materials). The radioactive materials are found in drill cuttings, drilling muds, brine, filter socks, scaling, and other flow back materials from the drilling processes. Essentially, TENORM result from processes where solids are separated from the fracking liquids for reuse. The process of separating the solids and liquids results in the radioisotopes settling out, or being filtered out, and concentrated, resulting in TENORM. Because of their radioactivity, fracking wastes containing TENORM must be handled and disposed of properly to protect public health.

Last updated in 2001, section 16 of 64CSR23 requires TENORM handling and processing to be compliant with radiation protection regulations. The Bureau proposes changes to the rule that do not add any new requirements. The changes are proposed to add clarity and specificity to the rule. The current rule addresses TENORM with radiation limits. The rule does not permit down blending to avoid regulation.

The Department notes that many comments received addressed section of the rule that have previously received Legislative approval, and are not included in modifications proposed by the Department. In particular, comments were received including text of the rule with modifications in ~~strikeout~~ and underline form. The responses below will address each section to which modifications were proposed.

#### **Comment:**

The Proposed Rule as written exceeds the scope of the DHHR's authority, resulting in duplicative regulatory oversight by multiple state agencies, therefore greater clarity is required to ensure the rulemaking is consistent with statutory authority.



**Response**

The Bureau works closely with personnel from WV Department of Environmental Protection (DEP) Water and Waste Management Sections in regulating TENORM facilities. No provisions of 64CSR23 duplicates any DEP rules.

**Comment**

The comment was submitted that oil and gas operations should be exempted from compliance with 64CSR23 because other applicable regulations adequately protect the environment.

**Response:**

The Department has reviewed the comment, and no changes were made. The purpose of 64CSR23 is for the protection of public health and is not aimed at environmental protection. While NRC rules address licensed radioisotope sources used in the drilling process, they do not regulate the naturally occurring radiation resulting from certain oil and gas operations. While the DEP does have regulatory oversight of the oil and gas industry, aside from solid waste disposal regulations, DEP rules do not address radiation safety or control radiation to protect public health. Further, DEP rules do not address the handling or processing of the materials to minimize possible exposures of employees and minimize environmental contamination during the processing.

**Comment:**

Regulation of TENORM from oil and gas activities, if any, should be undertaken by the WVDEP's OOG, Division of Air Quality and/or Division of Water and Waste Management.

**Response:**

The Department has reviewed the comment, and no changes were made. The rule addresses the handling and processing of the radiation contaminated materials produced by the industry, and does not address the process of oil and gas drilling.

**Comment:**

64CSR23 does not apply to TENORM waste that is destined for landfills and received by landfills and is therefore exempt.

**Response:**

The Department has reviewed the comment, and no changes were made. The DEP regulates material that is received and disposed at West Virginia landfills, but does not regulate the handling of these materials before they reach a landfill or which are abandoned.

**Comment:**

Scientific evidence, including a Pennsylvania study of TENORM, demonstrates that TENORM poses no imminent and substantial danger to the public health.

**Response:**

The Department has reviewed this comment, and no changes were made to the rule. While a singular low level exposure to TENORM may not pose a risk to public health, there is no "safe" level of radiation exposure as the risk of cancer is cumulative over a lifetime. The radioisotopes most often of concern in TENORM are Radium 226 and 228 have a half-life of 1600 years and are alpha emitters. Without proper handling and appropriate Personal Protective Equipment and good hygienic practices, these isotopes can be ingested inside the body, and do damage even at low levels. The oil and gas industry processes that concentrate the radiation can produce radiation levels that are much higher than background readings. Repeated spills of the liquids containing radiation can be tracked into vehicles, workspaces, and homes creating the risk of exposure beyond the industry worker.

A review of the Pennsylvania TENORM study regarding the risk of internal radiation exposures reveals that it was conducted only at well pad sites and not in the post-production handling of TENORM materials. However, post-production handling of TENORM often results in the most risk of exposure to radiation. In particular, inactive TENORM processing sites with much higher than background contaminated materials and equipment onsite can pose a threat to nearby homes and communities. Left unsecured, inactive



TENORM sites poses a risk to the community.

**Comment:**

The Proposed Rule's use of risk-based standards should be applied consistently throughout the rule.

**Response:**

The Department has reviewed the comment, and responds to the particular provisions identified in the comment below.

**Comment:**

The fiscal note preceding the proposed rule does not comply with the Administrative Procedures Act.

**Response:**

The Department has reviewed the comment and has determined that a fiscal note is not necessary because the rule does not add any new regulatory obligations.

**Comment:**

The proposed rule should clearly exempt wastes from wells drilled pursuant to Well Work Permits issued under Articles 6, 6A, and 21, Chapter 22 of the W. Va. Code to avoid any concerns about conflict with the Legislature's intent to have WVDEP regulate oil and gas activities.

**Response:**

The Department has reviewed this comment, which has been addressed above. No changes were made to the rule in response to this comment.

**Comment:**

The Proposed Rule should be revised to limit incorporation of 64CSR23 to provide much needed clarity for the regulated community.

**Response:**

The Department has reviewed the comment, and many of the suggested modifications were adopted in order to improve the clarity of the rule. Each specific proposal is addresses in the response to follow.

NOTE: The highlighted portions below contain the suggested change to the rule as filed.

**Comment**

**§64-23-16. Radiation Safety Requirements for Technologically Enhanced Naturally Occurring Radioactive Materials (TENORM).**

**Response**

The Department has reviewed this comment and accepts the suggested change.

**Section 3 - Definitions**

**Comment**

The following provision should be deleted: 3.105 Definition of Unrefined and Unprocessed ore: Ore in its natural form prior to any processing such as grinding, roasting, beneficiating, or refining.

**Response**

The Department has reviewed the comment and the provision was removed from the rule as duplicative.

**Section 16- TENORM**

**Comment**

**16.1 Purpose.** ~~This Section establishes radiation protection standards for the possession, use, transfer, and disposal of technologically enhanced naturally occurring radioactive materials (TENORM).~~ --- this section establishes radiation protection standards for Technologically Enhanced Naturally Occurring Radioactive



Material (TENORM). These standards include the possession, use, processing, manufacture, distribution, transfer, and disposal of TENORM and of products with TENORM. This section also provides for the licensing, registration of persons and entities possessing, using, processing, manufacturing, distributing, transferring and disposing of TENORM, including license-registration termination. The provisions of this section are in addition to the definitions and applicable requirements of all other provisions of this rule.

**Response**

The Department has reviewed this comment and accepts the changes to the extent that it adds specificity. However, the Department declines to strike out the very last sentence since applicable worker safety, public safety and transportation requirements are addressed in other sections of the rule.

**Comment**

16.2.c. The manufacture and distribution of products containing TENORM, in which the TENORM or its emitted radiation is considered to be ~~a beneficial attribute to the product~~, are registered under the provisions of section 11 of this rule.

**Response**

The Department has reviewed this comment and will modify the rule so that it reads as follows: The manufacture and distribution of products containing TENORM, in which the TENORM or its emitted radiation is considered to be a beneficial attribute or beneficial to the product, are registered under the provisions of section 11 of this rule.

**Comment**

16.3.a. ~~Beneficial Attribute -- the radioactivity of the product necessary to the use of the product.~~

**Response**

The Department has reviewed this comment and no changes were made to the rule as the term has significance elsewhere in the rule.

**Comment**

16.3.b. Beneficial to the Product -- the TENORM or its emitted radioactivity ~~of is beneficial to~~ the product necessary to the use of the product.

**Response**

The Department has reviewed this comment and will modify the rule to add the expanded definition of beneficial to the product.

**Comment:**

16.3.c. Critical group - the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

**Response:**

The Department has reviewed the comment and will modify the rule with the proposed definition.

**Comment**

16.3.d. ~~General~~ Environment -- the total terrestrial, atmospheric, and aquatic environments outside the site boundary within which any activity, operation, or process authorized by a general or specific registration issued under this section, is performed.

**Response**

The Department has reviewed this comment and has modified the rule to accept the suggested change.

**Comment**

16.3.e. Product -- something produced, made, manufactured, refined, or benefitted by the incorporation of TENORM or its emitted radioactivity, but does not include waste or byproduct material that may include radioactive material.

**Response**

The Department has reviewed this comment and partially accepts the expanded definition so that the wording



of the definition would read: Product -- something produced, made, manufactured, refined, or benefitted by the incorporation of TENORM or its emitted radioactivity. The remainder of the suggested changes are rejected because inclusion of the remainder of the suggested definition would remove some industrial activity where radiation is encountered and concentrated through manmade activities.

**Comment- Specific to oil and gas**

16.3.g. Technologically Enhanced Naturally Occurring Radioactive Material (TENORM) -- ~~naturally-occurring radionuclides whose concentrations are increased by or as a result of past or present human practices. TENORM does not include background radiation or the natural radioactivity of rocks or soils. TENORM does not include uranium or thorium in "source material" as defined in the AEA and US NRC regulations.~~ naturally occurring radioactive material in which radionuclide concentrations are increased by or as a result of past or present human practices. TENORM does not include background radiation or the natural radioactivity of rocks or soils. TENORM does not include "source material" and "byproduct material" as both are defined in the Atomic Energy Act of 1954, as amended (AEA 42 USC §2011 *et seq.*) and relevant regulations implemented by the NRC.

**Response**

The Department has reviewed this comment and accepts the suggested change.

**Comment**

16.3.h. Transfer -- ~~the physical relocation of NORM-containing materials not directly associated with commercial distribution within a business's operation or between general or specific registrants. This term does not include a change in legal title to NORM-containing materials that does not involve physical movement of those materials.~~ the physical relocation of TENORM within a business operation or between general or specific ~~licensees~~ registrants. This term does not include commercial distribution or a change in legal title to TENORM that does not involve physical movement of those materials.

**Response**

The Department reviewed this comment and accepts the change of terminology from licensee to registrant.

**Comment**

16.4.d. ~~TENORM waste regulated by CERCLA or RCRA (Resource Conservation and Recovery Act) are exempt from this Section. Persons who receive, possess, use, process, transfer, distribute or dispose of TENORM waste regulated by the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA 42 USC §9601 *et seq.* as amended) or by the Resource Conservation and Recovery Act (RCRA 42 USC §6901 *et seq.* as amended), the United States Department of Transportation, including, but not limited to, the Natural Gas Pipeline Safety Act, the Hazardous Liquid Pipeline Safety Act, and the Rail Safety Improvement Act, [insert cites], or by the West Virginia Division of Environmental Protection, including the Division of Air Quality, Division of Water and Waste Management and the Office of Oil and Gas are not subject to this section rule for that TENORM waste.~~

**Response**

The Department has reviewed this comment has modified rule accordingly to reflect the proper name of the Department of Environmental Protection. No other changes were made to the rule because none of the added regulatory agencies or documents pertain to radiation control measures which would protect employees and public health through control measures that would mitigate conditions prior to release of radiation.

**Comment – Specific to oil and gas**

16.4.e. The transportation and storage incident to transportation are governed by ~~§~~sections 6. and ~~164~~. of this rule.

**Response**

The Department has reviewed this comment and accepts the suggested change.

**Comment**

16.4.f. ~~Persons who receive, possess, or use, process, transfer, distribute, or dispose of TENORM shall~~



~~shall not be subject to the provisions of this section rule when a determination has been made by the agency, based on information provided by persons seeking to qualify for this exemption or otherwise, that the reasonably maximally exposed individual will not receive a public dose with a total effective dose equivalent (TEDE) of more than one millisievert (0.1 rem) in one year from all licensed or registered sources of radiation including TENORM.~~

**Response**

The Department has reviewed this comment and makes agrees to adding the qualifiers of receive, use, process, transfer, distribute or dispose of. ... However, the Department declines the remainder of the suggested changes.

**Comment**

16.4.g. Persons who receive, possess, transfer, or dispose of drill cuttings or waste containing TENORM arising from or related to well work permits authorized pursuant to articles 6, 6A or 21 of chapter 22 of the West Virginia Code.

**Response**

The Department has reviewed this comment and makes no change in response since drill cuttings and waste are known to have radiation contamination.

**Comment**

16.5.b. Persons subject to a specific registration under this section shall comply with radiation protection standards set out in section 6 [insert specific portions of section that are applicable] of this rule.

**Response**

The Department has reviewed this comment and no changes were made to the rule. All persons registered under this rule are responsible for following radiation protection standards as outlined in all of section 6.

**Comment**

16.6. Protection of Workers During Operations. Each person subject to a specific ~~or general~~ registration under this section shall conduct operations in compliance with the standards for radiation protection set out in the relevant sections 6 and 13 of this rule.

**Response**

The Department has reviewed this comment and no changes were made in response. All persons registered under this rule are responsible for following radiation protection standards as outlined in sections 6 and 13. These sections are specific to worker protection and their rights.

**Comment**

16.7. Release for Unrestricted Use and Conditional Release. Each person subject to a specific registration under this section shall:

**Response**

The Department has reviewed this comment and no changes were made to the rule. The provision should apply to any registration.

**Comment**

16.7.b. Not transfer or release for unrestricted use equipment contaminated with TENORM in excess of a surface gamma radiation level of < 100 microrems/hour ~~including~~excluding natural background; and

**Response**

The Department has reviewed this comment and accepts the suggested change.

**Comment**

16.7.c. Not transfer land for unrestricted use ~~unless one of the following apply: where the concentration of <sup>226</sup>Ra or <sup>228</sup>Ra in soil averaged over any one hundred (100) square meters exceeds the background level by more than one hundred eighty five (185) Becquerel per kilogram (five [5] pCi/gm); averaged over any fifteen (15) cm layer of soil below the surface, unless compliance with Ssubsection 16.5.b. through d. can be demonstrated.~~

**Response**



The Department has reviewed this comment and accepts the suggested change.

**Comment – Specific to oil and gas**

16.7.c.1. The average member of the critical group will not receive an annual public dose in excess of 0.25 millisievert (0.025 rem) TEDE from residual radioactive materials on site ~~other than including~~ residual TENORM <sup>226</sup>Ra and <sup>228</sup>Ra and their progeny.

**Response**

The Department has reviewed this comment and accepts the suggested change.

**Comment**

16.7.c.2. The concentration of residual TENORM <sup>226</sup>Ra and <sup>228</sup>Ra, on land averaged over 100 square meters, is less than 185 becquerel per kilogram (5 pCi/g) above the background concentration, averaged over the first ~~any~~ 15 cm layer of soil, or less than or equal to 15 pCi/g above the background concentrations averaged over subsequent 15 cm layers of soil below the first layer of soil. The 15 cm layers are contiguous depth increments from the surface down. Each of the progeny radionuclides of the residual TENORM <sup>226</sup>Ra and <sup>228</sup>Ra may also be present in concentrations similar to the residual TENORM <sup>226</sup>Ra and <sup>228</sup>Ra concentration; or

**Response**

The Department has reviewed this comment and no changes were made in response. Failure to test for radiation contamination below the top 15cm soil layer may result in future disturbances to radiation materials that exist in the subsequent layers of soil.

**Comment**

16.7.d. Specific ~~licensees-registrants~~ shall meet the requirements of sections 16.12, and 16.17 applicable to remediation and termination of the license.

**Response**

The Department has reviewed this comment and accepts the suggested change.

**Comment**

16.7.e. General ~~licensees-registrants~~ shall notify the agency in writing prior to commencing activities to reclaim the site. ~~Decontamination activities require a specific license.~~

**Response**

The Department has reviewed this comment and agrees with changing licensee to registrant. The Agency disagrees with striking the last sentence. However, in the last sentence, the word license should be changed to registration.

**Comment**

16.7.f. Notification of Site or Area Closure. General ~~licensees-registrants~~ permanently or for a period of two years ceasing the ~~use-possession~~ of radioactive materials at a site or portion of a site or facility, the ~~licensee-registrant~~ shall, within 60 days, provide the following information in writing to the agency:

**Response**

The Department has reviewed this comment and agrees with the suggested changes.

**Comment**

16.7.h. Conditional release of metal for recycle. Conditionally released metal for recycle shall be allowed only when metal contaminated with TENORM does not exceed a maximum exposure level of ~~50100~~ microrentgen per hour, ~~including-excluding~~ background radiation, at any accessible location of the metal surface prior to release from the site.

**Response**

The Department has reviewed the comment and makes no change in response. 50 microrentgen per hour is the national suggested standard by CRCPD and is approximately 2 ½ time background levels.



**Comment**

16.7.i. Equipment not released for unrestricted use. Equipment contaminated with TENORM in excess of levels specified in ~~Table 64-23~~ may be transferred pursuant to section 16.32.9.d.

**Response**

The Department has reviewed the comment and has modified the rule accordingly.

**Comment**

16.8.a. Each person subject to a registration under this rule, **unless exempt pursuant to 16.4.**, shall manage and dispose of wastes containing TENORM:

**Response**

The Department has reviewed the comment and has modified the rule accordingly.

**Comment**

16.8.a.1. By transfer of the wastes for disposal to a facility ~~registration under~~ subject to the requirements for uranium or thorium byproduct materials in either 40 CFR 192 or 10 CFR 40 Appendix A ~~or to a facility subject to regulation by the West Virginia Department of Environmental Protection;~~ or

**Response**

The Department has reviewed the comment and agrees to strike "registration under" and change to "subject to the." However, wording related to the WV Department of Environmental Protection (WVDEP) will not be incorporated since the WVDEP does not regulate sites that handle uranium and thorium byproduct materials.

**Comment**

16.8.a.3. By transfer of the wastes for disposal at a permitted solid or hazardous waste disposal facility, provided such facility is not prohibited from receiving and disposing such TENORM waste and the disposal is in accordance with applicable federal and state law; or

**Response**

The Department has reviewed the comment and has modified the rule accordingly.

**Comment**

16.8.a.4. By transfer of the wastes for disposal in another state as otherwise approved by the applicable governmental authority; or

**Response**

The Department has reviewed the comment and has modified the rule accordingly.

**Comment**

16.8.a.5. By disposal in an injection well approved in accordance with West Virginia Department of Environmental Protection regulations or at an out-of-state injection well approved by the applicable governmental authority

**Response**

The Department has reviewed the comment and has modified the rule accordingly.

**Comment**

16.8.a.~~36~~. In accordance with alternate methods authorized by the agency upon application or upon the agency's initiative, consistent with section 16.5 and where applicable the clean water act, safe drinking water act and other requirements of the US Environmental Protection Agency for disposal of such wastes.

**Response**

The Department has reviewed the comment and has modified the rule accordingly.



**Comment**

16.8.b. Equipment contaminated with TENORM in excess of levels specified in Table ~~64-23~~ 64-23 ~~64-23~~, which is to be disposed of as waste, shall be disposed of:

**Response**

The Department has reviewed the comment and has modified the rule accordingly.

**Comment**

16.8.b.2. ~~Within disposal areas specifically designed to meet the criteria of Subsection 16.8.a. Equipment contaminated with TENORM not exceeding a maximum exposure level of 100 microroentgen per hour, including excluding background radiation, at any accessible site may be disposed in a landfill that complies with W. Va. Code §22-15-8.~~

**Response**

The Department has reviewed the comment and no change was made in response. However, the Department found an error in this section. The 100 microroentgen should be 50 microroetgen.

**Comment**

~~16.8.c. Transfers of waste containing TENORM for disposal shall be made only to a person specifically authorized by the Nuclear Regulatory Commission, an agreement state or a licensing state, to receive such waste.~~

**Response**

The Department has reviewed the comment and has modified the rule accordingly.

**Comment**

16.8.~~de~~. Records of disposal, including manifests, shall be maintained pursuant to the provisions of section ~~6.38 and 6.41.f.~~ of this rule.

**Response**

The Department has reviewed the comment and has modified the rule accordingly.

**Comment**

16.8.~~ed~~. TENORM waste shall not be diluted for the sole purpose of making the waste exempt from the disposal requirements without prior agency approval. The criteria in section 16.5 shall be used by the agency to determine whether to approve such a request.

**Response**

The Department has reviewed the comment and has modified the rule accordingly.

**Comment**

16.8.~~fe~~. Drums or shipping containers of TENORM waste ~~transferred offsite for disposal~~ shall not exceed an average concentration of 50.0 picocuries per gram of Radium-226 plus Radium-228, unless the drums or shipping containers containing TENORM are utilized to transfer the TENORM for disposal in another state as approved by an applicable governmental authority; or in accordance with alternate methods authorized by the agency or other applicable state or federal agency.

**Response**

The Department has reviewed the comment and has modified the rule accordingly.

**Comment**

16.8.~~gf~~. Containers other than containers regulated pursuant to the West Virginia Aboveground Storage Tank Act, or kept at a facility less than 90 days and having a capacity greater than ~~insert capacity~~:

**Response:**

The Department has reviewed the comment and no changes were made. Many of the tanks used in the Oil



and Gas industry while required to be registered under the West Virginia Above Ground Storage Tank Act are not pursuant to inspection of the tanks for leaking of contained material, which may result in exposure to radioactive isotopes.

**Comment**

16.8.-ef.1. Containers containing TENORM waste shall be kept in a leak-proof container.

**Response**

The Department has reviewed this comment and has modified the rule with regard to numbering. The additional language improperly limits the scope of this provision and was not incorporated.

**Comment**

16.8.-ef.2. The registrant shall use a container made of, or lined with, materials that will not react with, or be incompatible with the TENORM waste to be stored so that the ability of the container to contain the waste is not impaired or compromised.

16.8.-ef.3. A container containing TENORM waste shall always be closed and sealed during storage or while in transport, except when it is necessary to add or remove waste.

16.8.-ef.4. A container containing TENORM waste may not be opened, handled, or stored in a manner that may rupture the container or cause it to leak.

16.8.-ef.5. At least quarterly, the registrant shall inspect areas where containers of TENORM waste are stored, inspecting for leaking or deteriorating containers or containment systems.

16.8.-ef.6. All containers of TENORM waste shall be stacked in such a manner that each container identification label can be read from the access aisle or area.

16.8.-ef.7. Each container of TENORM waste shall be labeled with the following information prior to storage:

**Response**

The Department has reviewed the comments has modified the rule with regard to numbering, but does not add the word waste to these provisions as the modification would unnecessarily narrow the application of the rule as to containers of TENROM.

**Comment**

16.8.-ef.7.A. Name and address of generator;

16.8.-ef.7.B. Type of material (e.g., sludge, scale, dirt, scrap metal, et cetera);

16.8.-ef.7.C. Date stored; and

16.8.-ef.8. The registrant shall develop a schedule, not less than quarterly, and procedure for assessing the condition of each container of TENORM. The schedule and procedure must be adequate to detect cracks, leaks, corrosion and erosion that may lead to cracks, leaks, or wall thinning to less than the required thickness to maintain vessel integrity. Procedures for emptying a waste container to allow entry, procedures for personnel protection, and inspection of the interior must be established when necessary to detect corrosion of the waste container sides and bottom. Records shall be maintained for a period of at least five years.

**Response**

The Department has reviewed the comment and has modified the rule accordingly.

**Comment**

16.8.-ef.7.D. Labeled as ~~radioactive material~~ TENORM waste.

**Response**

The Department has reviewed this comment and no changes were made in response as unnecessarily confusing to people who may handle the material.

**Comment – Specific to Oil and Gas**

16.8.-ef.8. The registrant shall develop a schedule, not less than quarterly, and procedure for assessing the



condition of each container of TENORM waste. The schedule and procedure must be adequate to detect cracks, leaks, corrosion and erosion that may lead to cracks, leaks, or wall thinning to less than the required thickness to maintain vessel/container integrity. Procedures for emptying a waste container to allow entry, procedures for personnel protection, and inspection of the interior must be established when necessary to detect corrosion of the waste container sides and bottom. Records shall be maintained for a period of at least five years.

**Response**

The Department has reviewed the comment and has modified the rule accordingly.

**Comment**

16.9.a. Subject to the requirements of sections 16.5 - 16.8 ~~and section 16.10~~, a general registration ~~is hereby issued~~ is hereby issued to persons who shall be required to possess, own, use, transfer, distribute or dispose of TENORM without regard to quantity which registration shall apply to every facility owned or operated by that person.

**Response**

The Department has reviewed this comment and no changes were made. Persons need to apply for registration and registration must be site specific.

**Comment**

16.9.b. ~~This~~ A general registration does not authorize the manufacturing of products containing TENORM in concentrations greater than those specified in section 16.4 nor the receipt and disposal of TENORM wastes from other persons.

**Response**

The Department has reviewed the comment and has modified the rule accordingly.

**Comment**

16.9.c. The decontamination of equipment, facilities, and land shall be performed only by persons specifically registered by the agency or another licensing state to conduct such work. However, employees or contractors under control and supervision of a general registration can perform ~~routine~~ maintenance on equipment, facilities, and land owned or controlled by the general registration. Maintenance that provides a different pathway for exposure than is found in daily operations and that increases the potential for additional exposure ~~is not considered routine must be performed in a manner that ensures exposures do not exceed levels allowable by this section.~~

**Response**

The Department has reviewed this comment and no changes were made to the rule. Employee protection to prevent unnecessary exposures through different exposure pathways needs to be undertaken only by those registered as Specific Registrant.

**Comment**

16.9.d.1.A. The equipment and facilities contaminated with TENORM or materials containing TENORM are to be used by the recipient for the same purpose or managed in a similar manner; or

**Response**

The Department has reviewed the comment and has modified the rule accordingly.

**Comment**

16.9.e. Distribution of TENORM products between general registrants. The distribution of TENORM products not exempt from this rule from one general registration to another general registrant is authorized provided the product is accompanied by labels or manifests or other relevant informational materials which identify the type and amount of TENORM.

**Response**



The Department has reviewed this comment and no changes were made in response as reducing clarity of the rule.

**Comment**

16.10. Specific Registration. Unless otherwise exempt, a person shall obtain a specific registration is required to which shall be applicable to each facility owned or operated by that person in order to:

**Response**

The Department has reviewed this comment and no changes were made as all registrations must be site specific.

**Comment**

16.10.a. Manufacture and distribute any TENORM material or consumer or retail product containing TENORM unless authorized by subsection 16.9.e, exempted under the provisions of section 16.4, or registered under the provisions of section 6 of this rule;

**Response**

The Department has reviewed the comment and has modified the rule accordingly.

**Comment**

16.11.a. Applications for specific registration shall be filed in a manner and on a form prescribed by the agency and include the registration fee as authorized pursuant to 64 CSR 51, Appendix B, Section 3.B.

**Response**

The Department has reviewed the comment and agrees with adding the reference to 64CSR51 but not the appendix and subsection as there are applicable fees in other sections that also apply.

**Comment**

16.11.d. An application for a specific registration may include a request for a registration authorizing applicable to one or more facilities, sites and activities.

**Response**

The Department has reviewed this comment and no changes were made as all registrations must be site specific.

**Comment**

16.12.a. A registration application will may shall be approved if the agency determines that:

**Response**

The Department has reviewed this comment and no changes were made in response as impermissibly eliminating discretion of the agency.

**Comment**

16.12.a.1. The applicant is qualified by reason of training and experience to use or manage the TENORM in question for the purpose, or in the manner, requested in accordance with this rule in such a manner as to protect the public health and safety or property;

**Response**

The Department has reviewed the comment and will add the words "or manage."

**Comment**

16.12.a.4. The applicant satisfied all applicable special requirements in this section; and

**Response**

The Department has reviewed the comment and has modified the rule accordingly.



**Comment**

16.12.b. An application for a specific registration to decontaminate equipment, land, or facilities contaminated with TENORM in excess of the levels set forth in subsections 16.4.a, 16.7.b, or Table ~~64-23 Gg~~64-23 Hh, as applicable, and to dispose of the resulting waste will be approved if:

**Response**

The Department has reviewed the comment and has modified the rule accordingly.

**Comment**

~~16.12.b.2.E. For each site to be listed on the specific registration as an authorized site, the applicant shall submit either:~~

**Response**

The Department has reviewed the comment and has determined that further clarification is needed. The section should read: 16.12.b.2.E. For each site listed on the application, the applicant shall submit either:

**Comment**

16.12.c.1. The applicant satisfies the general requirements specified in subsection 16.~~23~~22.a;

**Response**

The Department has reviewed the comment and has modified the rule accordingly.

**Comment**

16.13.a. In normal use and disposal of a single exempt item, and in normal handling and storage of the quantities of exempt items likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, it is unlikely that the TEDE in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will not exceed the doses in Column I of ~~Table 64-23 Hh~~ 16-14.

**Response**

The Department has reviewed the comment and has modified the rule accordingly.

**Comment – Specific to Oil and Gas**

16.13.b. In use and disposal of a single exempt item and in handling and storage of the quantities of exempt items likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, the probability is low that the containment, shielding, or other safety features of the product would fail under such circumstances that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column II of the Table ~~64-23 Hh~~ in Subsection 16-14 and the probability is negligible that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column III of the Table ~~64-23~~ in Subsection 16-14Hh.

**Response**

The Department has reviewed the comment and has modified the rule accordingly.

**Comment - Specific to Oil and Gas**

16.14. Table of Organ Doses refer to Table 64-23 Hh.

**Response**

The Department has reviewed the comment and has modified the rule accordingly.

**Comment**

16.15.a. Upon a determination that an application meets the requirements of this rule, the agency ~~will~~may~~shall~~ issue a specific registration authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

**Response**



The Department has reviewed the comment and no change was made in response as improperly eliminating agency discretion.

**Comment**

16.15.b. The agency may incorporate in any license-specific registration at the time of issuance, or thereafter by amendment, such additional requirements and conditions with respect to the registrant's receipt, possession, use, and transfer of TENORM subject to this section as it deems appropriate or necessary in order to:

16.15.b.2. Require such reports and the keeping of such records, and to provide for such inspections of activities under the license-specific registration as may be appropriate or necessary; and

**Response**

The Department has reviewed the comment and has modified the rule accordingly.

**Comment**

16.16.a.1. Each specific registration issued pursuant to this section shall be subject to all the provisions of this rule, now or hereafter in effect, and to all rules, and orders of the agency.

16.16.a.2. No specific registration issued or granted under this section and no right to possess or utilize TENORM granted by any specific registration issued pursuant to this section shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any specific registration to any person unless the agency shall, after securing full information, find that the transfer is in accordance with the provisions of this rule, and shall give its consent in writing.

16.16.a.5. Each specific registrant shall:

16.16.a.5.A.1. A specific registrant;

16.16.a.5.A.2. An entity controlling a specific registrant or listing the specific registration or specific registrant as property of the estate; or

16.16.a.5.A.3. An affiliate of the specific registrant.

16.17.c.1. Submit an application for specific registration renewal under section 16.18; or

16.17.c.2. Notify the agency in writing, under subsection 16.17.b, if the specific registrant decides to discontinue all activities involving TENORM.

16.17.d. If a specific registrant does not submit an application for specific registration renewal under subsection 16.18., the specific registrant shall, on or before the expiration date specified in the specific registration:

16.17.d.4. Submit a report of disposal of TENORM and radiation surveys to confirm the absence of TENORM or to establish the levels of residual TENORM contamination. The specific registrant shall, as appropriate:

16.17.d.5. If levels of residual activity are less than those established in section 16.7, the specific registrant shall so certify. If the agency determines that this certification and the information submitted under subdivision 16.17.d.4 is adequate and surveys confirm the findings, the agency will notify the specific registrant in writing that the registration is terminated.

16.17.e. Each specific registrant who possesses residual TENORM under subdivision 16.17.d.6, following the expiration date specified in the specific registration, shall:

16.17.e.2. Continue to control entry to restricted areas until the locations are suitable for release for unrestricted use and the agency notifies the specific registrant in writing that the specific registration is terminated.

16.19. Amendment of Specific Registrations at Request of Registrant. Applications for amendment of a specific registration shall be filed in accordance with section 16.11 and shall specify the respects in which the registrant desires the specific registration to be amended and the grounds for such amendment.

16.20. Agency Action on Applications to Renew and Amend Specific Registrations. In considering an application by a specific registrant to renew or amend the specific registration, the agency will apply the criteria set forth in section 16.12.

**Response**

The Department has reviewed the comments and has modified the rule accordingly.



**Comment**

16.16.a.6. Each specific registrant licensee shall notify the agency in writing prior to commencing activities to reclaim the licensed a listed facility and site.

**Response**

The Department has reviewed the comment and accepts the change of wording for specific registrant. But rejects the suggested wording of "a listed" and instead substitutes "a registered".

**Comment**

16.16.a.3. Each person registered by the agency pursuant to this section shall confine use and possession of the TENORM ~~registered~~ to the locations and purposes authorized in the specific registration.

**Response**

The Department has reviewed the comment and agrees with the change.

**Comment – Specific to oil and gas**

16.16.a.4. Each person registered by the agency pursuant to this section is subject to the general license provisions of sections 16.6, 16.7 and 16.8.

**Response**

The Department has reviewed the comment and has modified the rule accordingly.

**Comment**

16.16.a.7. Notification of Site or Area Closure. When a specific registrant licensee has permanently ceased use of TENORM and all other radioactive materials at a site or portion of a facility and the specific registrant licensee has not decontaminated the area, or when an area has not been used for a period of two years, the specific registrant licensees shall, within 60 days, provide the following information in writing to the agency:

**Response**

The Department has reviewed the comment and has modified the rule accordingly.

**Comment**

16.17.a. Except as provided in subdivision 16.17.d.6 and subsection 16.18.b, each specific registration shall be effective for a term of five years and shall expire at the end of the specified day in the month and year stated therein. Any expiration date on a specific licensee registration applies only to the authority to engage in licensed designated facilities, sites or activities. Expiration of a specific license registration shall not relieve the licensee-registrant of responsibility for decommissioning its facility and terminating the specific license registration.

**Response**

The Department has reviewed the comment and has modified the rule to change the words "license" to "registration" and "licensee" to "registrant." The duration of the license was not incorporated as unnecessarily changing the operation of the rule.

**Comment**

16.17.b. Each specific registrant shall notify the agency in writing and request termination of the specific registration when the specific registrant decides to terminate all activities involving TENORM authorized under the specific registration. This notification and request for termination of the specific registration must include the reports and information specified in subdivision 16.17.d.6, if applicable. The registrant is subject to the provisions of subsections 16.17.d and 16.17.e, as applicable.

**Response**

The Department has reviewed the comment and has modified the rule accordingly.



**Comment**

16.17.d.3. Properly dispose of TENORM waste; and

**Response**

The Department has reviewed the comment and has modified the rule accordingly.

**Comment**

16.17.d.6. If levels of residual TENORM are not in conformance with criteria established in section 16.17, the specific registration continues in effect beyond the expiration date, if necessary, with respect to possession of residual TENORM until the agency notifies the specific registrant in writing that the specific registration is terminated. During this time, the specific registrant is subject to the provisions of subsection 16.17.e In addition to the information submitted under subdivision 17.d.4 16.17d.4, the specific registrant shall submit a plan, if appropriate, for decontaminating the location or locations and disposing of the residual TENORM.

**Response**

The Department has reviewed the comment and has modified the rule accordingly.

**Comment**

16.18.a. Applications for renewal of specific registrations shall be filed in accordance with section 16.11 and section 16.17.c.1.

**Response**

The Department has reviewed the comment and has modified the rule accordingly.

**Comment**

16.18.b. In any case in which a specific registration, not less than 30 days prior to expiration of an existing specific registration, has filed an application in proper form for renewal or for a new specific registration authorizing the same activities, such existing specific registration shall not expire until final action by the agency.

**Response**

The Department has reviewed the comment and has modified the rule accordingly.

**Comment**

~~16.21.a. The terms and conditions of all specific registrations shall be subject to amendment, revision, or modification or the specific registration may be suspended or revoked by reason of amendments to this rule, or by reason of rules, regulations, and orders issued by the agency.~~

**Response**

The Department has reviewed the comment and no change was made to the rule as improperly eliminating the ability of the agency to enforce the rule through administrative action.

**Comment**

16.21 ba. Any specific registration may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any materially false statement of fact required under provisions of this rule, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the agency to refuse to grant a specific registration on an original application, or for violation of, or failure to observe any of the applicable and substantive terms and conditions of this rule, or of the specific registration, or of any rule, regulation, or order of the agency.

**Response**

The Department has reviewed the comment and no changes were made. The suggested additions to this provision are issues that would more properly be raised in a challenge to administrative action.



**Comment**

16.21.~~eb~~. Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, the agency shall not modify, suspend or revoke a specific registration prior to the institution of proceedings unless facts or conduct which may warrant such action shall have been called to the attention of the specific registrant in writing and the specific registrant shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

**Response**

The Department has reviewed the comment and has modified the rule accordingly.

**Comment**

16.22. Reciprocal Recognition of Specific Registrations. Subject to this rule, any person who holds a specific registration or similar specific license from an agreement state or a licensing state, and issued by the agency having jurisdiction where the specific registrant maintains an office for directing the registered activity and at which radiation safety records are normally maintained, is hereby granted a general registration to conduct the activities authorized in such registering document within this state for a period not in excess of 180 days in any calendar year provided that:

**Response**

The Department has reviewed the comment and no changes were made to the rule as unnecessary to the administration of this provision.

**Comment**

16.22.b. The out-of-state registrant or licensee notifies the agency in writing at least three days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the State, and shall be accompanied by a copy of the pertinent registering document. If, for a specific case, the three day period would impose an undue hardship on the out-of-state registrant or licensee, the registrant may, upon application to the agency, obtain permission to proceed sooner. The agency may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general registration provided in subsection 16.22.a;

16.22.c. The out-of-state registrant or licensee complies with all applicable rules of the agency and with all the terms and conditions of the registering document, except any such terms and conditions which may be inconsistent with applicable rules of the agency;

16.22.d. The out-of-state registrant or licensee supplies such other information as the agency may request; and

16.22.e. The out-of-state registrant or licensee shall not transfer or dispose of TENORM possessed or used under the general registration provided in subsection 16.22.a except by transfer to a person:

**Response**

The Department has reviewed the comment and has modified the rule accordingly.

**Comment**

16.23. Financial Surety Arrangements for Specific Registrations. Pursuant to ~~§64 CSR 23, e~~ Each specific registrant or applicant for a specific registration under section 16.12 shall post with the agency financial surety, or security, to ensure the protection of the public health and safety and the environment in the event of abandonment, default, or other inability or unwillingness of the specific registrant to meet the requirements of this rule. Financial surety arrangements shall:

**Response**

The Department has reviewed the comment and has modified the rule accordingly.

**Comment**

16.23.b. Be in an amount sufficient to meet the applicant's or registrant's obligations ~~under the act and this rule for remediation of applicable registered the facility or facilities, land, and equipment, and shall be a minimum of \$1,000,000.00, unless~~ based upon agency approved cost estimates, ~~an additional amount is~~



~~necessary for remediation;~~

**Response**

The Department has reviewed the comment and no change was made to the rule. The Department is aware of TENORM sites have operated without permit and have been abandoned with radiation contamination. Without proper financial security, abandoned TENORM sites become a legacy of remediation costs to the citizens of West Virginia. The one million minimum financial security is a reasonable estimate for radiation cleanup costs for an abandoned site and is not out of line with financial surety costs required for other industries or other states.

**Comment**

16.23.c. Be established prior to issuance of the registration or the commencement of operations to assure that sufficient funds will be available to carry out the decontamination and decommissioning of the facility or facilities;

**Response**

The Department has reviewed this comment and no changes were made in response. All registrations must be site specific.

**Comment**

~~16.23.f. Be established within 90 days of July 1, 2001 for registrations in effect on that date.~~

**Response**

The Department has reviewed the comment and has modified the provision accordingly.





August 5, 2020

Bureau of Public Health  
West Virginia Department of Health and Human Resources  
ATTN: April L. Robertson  
e-mail: april.l.robertson@wv.gov  
One Davis Square, Suite 100 East  
Charleston WV 25301

Dear Ms Robertson

Waste Management of West Virginia (WMWV) is submitting the following comments on the Proposed Rule on "Radiological Health," 64 C.S.R. 23. Attached is a marked-up copy of the Rule with our comments highlighted.

Specifically, it is our interpretation that the Rule does not apply to landfills regulated by the WVDEP Solid Waste Program. Exemption Section 16.4.d states Persons who possess TENORM waste regulated by the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA 42 USC §9601 et seq. as amended) or by the Resource Conservation and Recovery Act (RCRA 42 USC §6901 et seq. as amended) or by the West Virginia Division of Environmental Protection are not subject to this section for that TENORM waste.

Since Non-hazardous Waste is regulated under RCRA and landfills are permitted under RCRA subtitle D requirements which the WVDEP (equivalent State authority) has adopted it is clear that TENORM destined for landfills and received by landfills is exempt.

Attached is a marked-up version of the draft rule with further comments for your consideration

WMWV respectfully requests that the Department consider WMWV's comments and implement WMWV's suggestions as submitted. WMWV appreciates the opportunity to comment on the Proposed Rule. Please do not hesitate to contact us should you have any further questions.

Regards

A handwritten signature in black ink, which appears to read 'Sandra DiSalvo', is positioned below the 'Regards' text.

Sandra DiSalvo



**West Virginia Oil and Natural Gas Association  
and  
Independent Oil and Gas Association of West Virginia, Inc.**

**Joint Comments to the Proposed Revisions to Legislative Rule, 64 C.S.R. 23,  
"Radiological Health"**

To: Bureau of Public Health  
West Virginia Department of Health and Human Resources  
ATTN: April L. Robertson  
e-mail: [april.lrobertson@wv.gov](mailto:april.lrobertson@wv.gov)  
One Davis Square, Suite 100 East  
Charleston WV 25301

West Virginia Oil & Natural Gas Association ("WVONGA") and Independent Oil & Gas Association of West Virginia, Inc. ("IOGA") appreciate the opportunity to submit the following joint comments on the proposed revisions to legislative rule, "Radiological Health," 64 C.S.R. 23 ("Proposed Rule"). The Proposed Rule was submitted to the West Virginia Secretary of State on July 6, 2020, including a notice that written comments must be submitted to the West Virginia Department of Health and Human Resources, Bureau of Public Health ("DHHR") by 5:00 p.m. August 5, 2020. WVONGA and IOGA (sometimes jointly referred to herein as "Commenters" or "the Associations") are recognized as representing virtually the entire oil and gas industry in West Virginia and appreciate the opportunity to submit their joint comments to the Proposed Rule. These comments are submitted without prejudice to any member of one or both Associations submitting comments, including comments that may be inconsistent with these comments, concerning the Proposed Rule.

**The Associations**

Chartered in 1915, WVONGA is one of the oldest trade organizations in West Virginia, and serves the entire oil and gas industry. The activities of WVONGA members include construction, environmental services, drilling, completion, gathering, transporting, distribution and processing. WVONGA members operate in almost every county in West Virginia and employ thousands of people across the State, with payrolls totaling hundreds of millions of dollars annually. Members have cumulative investment of nearly ten billion dollars in West Virginia, account for most of the production and recent well work permits, operate more than 20,000 miles of pipeline across the state and provide oil and natural gas to more than 300,000 West Virginia homes and businesses. As such, WVONGA's members have a keen interest in all aspects of health and environmental regulation associated with oil and gas activities, including the Proposed Rule.

Formed in 1959, IOGA is a statewide nonprofit trade association that represents companies engaged in the extraction and production of natural gas and oil in West Virginia, as well as the companies that support these extraction and production activities. IOGA was formed to promote



and protect a strong, competitive and capable independent natural gas and oil producing industry in West Virginia, while also protecting the natural environment of our state. IOGA has been in existence during times of boom and bust and its members have a long history of driving innovation in exploration and development of West Virginia's oil and gas reserves. IOGA members operate in virtually every county in West Virginia and have a longstanding tradition of working with the West Virginia Department of Environmental Protection ("WVDEP") and other state agencies to help regulators understand existing operations and new innovations and how to effectively regulate new technologies in a manner that protects public health and the environment while promoting the economic development so crucial to West Virginia.

It is in this spirit of experience and partnership with DHHR that the Associations offer these comments.

## **Introduction**

The Associations' primary focus in these comments relate to Section 16 titled "Radiation Safety Requirements for Technologically Enhanced Radioactive Material,"<sup>1</sup> and the potential application of this section to oil and gas wastes including, but not limited to, drill cuttings, produced water, tank bottoms and sediments. Section 16 of the Proposed Rule appears to be a much more reasonable substitute for DHHR's 2017 proposed legislative rule titled "Technologically Enhanced Naturally Occurring Radioactive Material," 64 C.S.R. 23A ("2017 Proposed Rule"). The Associations opposed the 2017 Proposed Rule due to its broad nature and it was ultimately withdrawn by DHHR in September 2017. The Associations acknowledge that the current Proposed Rule is more moderate in scope and recognizes that it follows, to some extent, the recommendations in Part N (2004) of the Conference of Radiation Control Program Directors, Inc.'s ("CRCPD") "Suggested State Regulations for Control of Radiation." In particular, the definition of TENORM conforms to the CRCPD definition and represents an appropriate, reasonable and manageable description of the broad category of TENORM. The Associations support this change to DHHR's consideration of how to properly define TENORM.

While the Associations support DHHR's efforts to protect the human health and its efforts to align the Proposed Rule with the framework of the CRCPD, the Associations request that DHHR revise and clarify certain aspects of the rule to: (i) avoid duplicative regulatory oversight by multiple state agencies that seems to conflict with the intent of the West Virginia Legislature; (ii) expand upon the potential economic impact of the Proposed Rule; and (iii) revise to prevent inconsistencies within the Proposed Rule.

### **A. General Comments**

As an initial matter, the Associations and their members recognize the critical importance of the safe and effective exploration, drilling and operation of oil and gas wells, consistent with the protection of human health and environment. Decades of experience in developing oil and gas resources in West Virginia and across the United States--as well as numerous scientific studies

---

<sup>1</sup> Consistent with the Associations attached comments to the text of the Proposed Rule, we note that the words "Naturally Occurring" should be inserted before the word "Radioactive" in the title of Section 16 to more accurately reflect the scope of the proposed rule.



and reviews--demonstrate that the environmental risks from TENORM in oil and gas well operations are already adequately managed. This knowledge includes shale development utilizing new drilling and completions techniques.

The Associations do not believe that the Proposed Rule will generally apply to oil and gas operations, as these operations generally do not receive, own, possess, use, process, transfer, distribute, or dispose of TENORM at or above the exposure limit listed in Section 16.4.f. of the Proposed Rule. Additionally, TENORM wastes generated by the oil and gas industry are subject to regulation by the WVDEP Division of Water and Waste and are therefore exempt under Section 16.4.d. of the Proposed Rule. However, additional clarity is required to provide certainty to the regulated community and clearly delineate the regulatory authority of DHHR vis-a-vis the WVDEP, particularly with respect to the management, storage, transportation and disposal of exploration and production (E&P) wastes (e.g., drill cuttings, completions waste, tank bottoms, and produced water). The Proposed Rule has the potential to significantly impact oil and gas operations with duplicative regulations that directly conflict with the express grants of statutory authority the West Virginia Legislature made to the WVDEP with respect to oil and gas wastes, unless the Associations' recommended revisions are made. Nonetheless, the Associations support DHHR's use of risk-based standards for regulating TENORM, which serve to protect human public and worker health and safety, while still providing regulated entities with flexibility in demonstrating compliance. Such risk-based standards should be applied consistently throughout the Proposed Rule, as they are generic to all forms of TENORM. The inconsistent application of concentration-based standards in some sections and risk-based standards in others should be rectified. (see e.g., Sections 16.4.f. 16.7.c.1 and 16.5.d. of the Proposed Rule).

Accordingly, the Associations request that certain exemptions and provisions be revised to prevent duplicative oversight by DHHR and WVDEP's Office of Oil and Gas ("OOG") and Division of Water and Waste Management ("DWWM"), and to avoid unnecessary regulatory burdens.

- 1. The Proposed Rule as written exceeds the scope of the DHHR's authority, resulting in duplicative regulatory oversight by multiple state agencies, therefore greater clarity is required to ensure the rulemaking is consistent with statutory authority.**

While the DHHR cites W.Va. Code § 16-1-4 as authority for the Proposed Rule in the forms filed with the West Virginia Secretary of State's office, DHHR should clarify the authority upon which it asserts the Proposed Rule is necessary and appropriate. While DHHR has the authority to regulate to protect human health, as identified in Section 16-1-6, the Proposed Rule as currently written encroaches on WVDEP's authority to regulate oil and gas operations and solid waste resulting therefrom, including E&P wastes.

Section 16-1-4 authorizes the Secretary to propose rules in accordance with the West Virginia Administrative Procedures Act ("APA") to regulate (1) the sanitary condition of various institutions, public and private; (2) occupational and industrial health hazards and the sanitary conditions (e.g., the regulation of sewage) of waters and water treatment systems, as well as public swimming pools; and (3) food and drug standards. *See generally* W.V. Code 16-1-4(b)(2)-(3), (5).



Similarly, Section 16-1-6 identifies the powers and duties of the DHHR Commissioner, which, at their most expansive, include the power to: (1) inspect sanitary conditions of certain private and public institutions to enforce rules related to sanitary conditions; (2) inspect and enforce legislative rules concerning occupational health and industrial health hazards and the sanitary condition of waters.

The Associations acknowledge DHHR's express authority to regulate the areas identified above. However, the express grants of rulemaking authority the legislature included in DHHR-applicable statutes does not appear to provide a basis for the Proposed Rule's extensive regulation of TENORM; particularly as it would relate to E&P waste disposal. The Proposed Rule does not seek to regulate "sanitary conditions," "food and drug standards" or even any "occupational and industrial health hazards" as authorized by Section 16-1-4. DHHR has not identified any occupational or industrial health hazard requiring regulation. The existence of TENORM in and of itself does not constitute either a "sanitary condition" or "occupational or industrial health hazard" as the existing science on this issue, as discussed further below, demonstrates that there is little risk of exposure to the public or workers from any naturally-occurring radioactive material in E&P wastes. Moreover, per Section 16-1-4(b)(8), fees may only be assessed for permits or services that properly relate to activities that the DHHR is lawfully authorized to regulate. Thus, regulation of TENORM and its environmental impacts associated with the oil and gas operations, including any registration or required fees, generally seems to be beyond the scope and authority of DHHR pursuant to Chapter 16 of the West Virginia Code.

Promulgated pursuant to the West Virginia Horizontal Well Act and the Solid Waste Management Act and other environmental-focused statutes, the WVDEP's OOG already has an existing comprehensive regulatory scheme for regulating oil and natural gas exploration, production, and development. Thus, to the extent the Proposed Rule would result in the regulation of oil and gas operations and the management and disposal of E&P wastes, such regulation would not appear to align with the scope of DHHR's specific or general rulemaking authority. Notably, in 1994, the West Virginia Legislature removed Articles 20 and 26 from Chapter 16—DHHR's enabling statute—which, prior to the revision, gave DHHR the power to regulate air pollution and solid waste management. These provisions were moved to Chapter 22, which created WVDEP as the sole agency authorized to create environmental regulatory programs.<sup>2</sup> This transfer of authority is further evidence that DHHR does not have authority to regulate the environmental impacts of air pollution or solid waste management. Rather, DHHR is authorized to regulate human exposure to radiation; the Solid Waste Management Act ("SWMA") specifically states DHHR is *only* given authority to enforce public health laws over solid waste which presents an imminent and substantial endangerment to the public health. W. Va. Code §22-15-4. The Proposed Rule exceeds DHHR's authority with respect to oil and gas operations by creating waste disposal regulations utilizing environmental metrics and addressing environmental impacts where no imminent and substantial endangerment to the public health exists.

Furthermore, waste disposal regulations for oil and gas waste containing radium already exist. Specifically, the Solid Waste Management Rule ("SWMR") implemented by WVDEP properly regulates the disposal of solid waste that may be classified as TENORM and allows

---

<sup>2</sup> W. Va. Code §22-1-1(b)(2) (stating that WVDEP was created "[t]o consolidate environmental regulatory programs in a single state agency").



disposal of drill cuttings and drilling waste that contain a combined concentration Ra-226 and Ra-228 at less than 5pCi/g above background levels (33 CSR § 1-5.6.d.4) and completions and production wastes that contain a combined concentration of Ra-226 and Ra-228 at less than 50 pCi/g at commercial solid waste facilities. (33 CSR § 1A.3.4.b). Thus, the Proposed Rule, as potentially applied to oil and gas wastes, not only exceeds DHHR's regulatory authority, but it is also duplicative of existing regulations.

Section 16.7.h of the Proposed Rule attempts to regulate the exposure level of metals that can be released from the site for recycling at a level of 50 µR/hr. However, regulations pertaining to metals recycling in West Virginia fall under the definition of "salvage yards" as defined in the WVDEP Solid Waste Regulations under 33 CSR § 1-2.109, and as such should be exempt from the scope of DHHR's Proposed TENORM Rule. Additionally, various agencies including WVDEP and USDOT regulate the storage, disposal and transport of materials containing TENORM, and therefore Sections 16.8.f. and 16.8.g of the Proposed Rule are duplicative and should be revised in accordance with these comments.

To the extent DHHR intends that the Proposed Rule apply to oil and gas operations, the Association's believe such regulation is simply not supported by the statutory authority cited by DHHR. Accordingly, the Proposed Rule should be revised to specifically exclude persons possessing drill cuttings, completions waste, produced water, and other E&P waste arising from or related to well work.

**2. Regulation of TENORM from oil and gas activities, if any, should be undertaken by the WVDEP's OOG, Division of Air Quality and/or Division of Water and Waste Management.**

The WVDEP, primarily through its OOG, Division of Air Quality ("DAQ") and Division of Water and Waste Management ("DWWM"), currently regulates every aspect of oil and natural gas exploration, production, and development in West Virginia. There are numerous permitting, reporting, and recordkeeping obligations in those regulations that serve as the functional equivalent to many of the requirements of the Proposed Rule potentially applicable to oil and gas wastes. The statewide regulatory programs, administered by the OOG, DAQ, and DWWM, provide consistency across the State in conformity with the purpose for which the DEP was created. The West Virginia Legislature expressly recognized the need for uniformity and consistency with respect to enforcement of the environmental law in our State in Section 22-1-1(a)(5) of the West Virginia Code, declaring that

"[t]hose functions of government which regulate the environment should be consolidated in order to accomplish the purposes set forth in this article, to carry out the environmental functions of government in the most efficient and cost effective manner, to protect human health and safety and, to the greatest degree practicable, to prevent injury to plant, animal and aquatic life, improve and maintain the quality of life of our citizens, and promote economic development consistent with environmental goals and standards."



This declaration of policy by the West Virginia Legislature underscores the importance of uniformity and regulatory consistency for business growth and economic development in West Virginia. Without a uniform and consistent approach to the regulation of oil and natural gas across the State, growth and expansion of our industry will be impeded, and employment and economic benefits will be lost. The Associations recognize that this is not the intention of the Proposed Rule, but believe it must be taken into account during this rulemaking process.

The West Virginia SWMA (W. Va. Code § 22-15-1) allows for commercial solid waste facilities to lawfully receive drill cuttings and associated drilling waste generated from horizontal well sites within certain parameters. The express purpose of the SWMA is to “establish a comprehensive program of controlling all phases of solid waste management.” W. Va. Code §22-15-1(a). The Legislature intended to give the WVDEP exclusive authority to regulate the disposal of E&P wastes. To this end, WVDEP promulgated the SWMR, which allows disposal of drill cuttings and drilling waste that contain a combined concentration of Ra-226 and Ra-228 at less than 5 pCi/g above background levels at commercial solid waste facilities under 33 CSR §1-5.6.d.4. Additionally, in 2017 WVDEP promulgated rules regulating the disposal of completions and production wastes that contain a combined concentration of Ra-226 and Ra-228 at less than 50 pCi/g above background levels at commercial solid waste facilities under 33 CSR § 1A, further reinforcing the WVDEP DWWM authority over all aspects of E&P wastes. Thus, DHHR’s Proposed Rule, if intended to apply to drilling and other oilfield wastes, would result in unnecessary duplicative oversight by DHHR and WVDEP.

Additionally, the Legislature, through the SWMA, tasked the WVDEP with conducting an investigation and authoring a report examining the hazardous characteristics of leachate from solid waste facilities receiving drill cuttings and drilling waste, which included the presence of radium and radon; the technical and economic feasibility and benefits of establishing additional and/or separate disposal locations which are funded, constructed, owned and/or operated by the oil and gas industry; and viable alternatives for the handling, treatment, and disposal of drill cuttings. W. Va. Code §22-15-8(j). This was completed in 2015. This further demonstrates the Legislature’s belief that the WVDEP, not the DHHR, is the proper authority to regulate, research, and provide findings regarding any possible hazardous characteristics of drilling waste and the handling and disposal of that waste, including with respect to TENORM.

**3. Scientific evidence demonstrates that TENORM poses no imminent and substantial danger to the public health.**

The DHHR states that the “[a]mendments are designed to increase efficacy of the regulatory program, without which the state will shoulder the burden of radiological health effects from TENORM and may be left with legacy costs of site remediation.” However, those concerns do not apply to TENORM in oil and gas waste because of the existing, comprehensive WVDEP regulatory scheme explained above. Moreover, multiple state environmental agencies that regulate oil and gas activities in the Marcellus Shale have conducted independent investigations and concluded that there is little potential for radiation exposure to workers and members of the public related to oil and gas drilling and completion activities. These studies demonstrate that additional regulation of oil and gas operations by DHHR is not necessary.



West Virginia's own 2015 report, titled "Final Report on the Examination of Drill Cuttings and Related Environmental, Economic, and Technical Aspects Associated with Solid Waste Facilities in West Virginia," which includes the Marshall University Center for Environmental, Geotechnical and Applied Sciences study of Radioactivity Associated with Marcellus Shale Exploration and Disposal of Related Material (collectively, "WVDEP Report"), only reinforces that TENORM in all types of oil and gas waste is currently regulated adequately. The WVDEP Report reflects results of studied radioactivity of leachate at a numerous landfills, some that accepted drill cuttings and some that did not accept them. Drill cuttings were also collected and analyzed; two sets from vertical drilling operations and three from horizontal Marcellus Shale wells. The study found that drill cuttings from the Marcellus Shale formation contain radioactive compounds at levels higher than the overlying strata, and are likely contributing to radioactive compounds present in landfill leachate. However, the study revealed that radioactive compounds were present at both types of landfills (one with, and one without, drill cuttings), and landfills that accept drill cuttings are already required to sample for radioactive materials once a month per WVDEP regulation.

These sample results were analyzed to determine any statistical trends and no radioactive constituent showed evidence of accelerated increase over time. Rather the constituents showed steady levels or normal up-down fluctuations over time. The study concluded that radioactive compound levels in landfill leachate are at similar levels at both landfills that accept drill cuttings, and landfills that do not accept drill cuttings. Thus, the WVDEP Report revealed that TENORM present in oil and gas wastes was not accumulating at solid waste disposal facilities so as to present greater risk of radioactive contamination as compared to disposal facilities that did not accept F&P wastes. As a result of finding that TENORM in oil and gas wastes did not present significant unique risks, the WVDEP Report ultimately recommended that monitoring for radiological compounds in landfill leachate should continue but that, notably, the frequency of monitoring should be reduced.

Moreover, other states have examined the risk of TENORM's presence directly at oil and gas operational sites; these states have reached similar conclusions regarding no need for additional regulation. For example, the Pennsylvania Department of Environmental Protection's ("PADEP") report titled "Technologically Enhanced Naturally Occurring Radioactive Materials (TENORM) Study Report" published in January 2015 and revised in May 2016, ("PADEP Report"), provides further evidence that there is no threat to human health from TENORM associated with oil and gas operations and there is no need for further regulation of oil and gas industry related TENORM.<sup>3</sup>

The PADEP Report includes observations made at well sites, and concludes as follows:

- There is little potential for internal radiation exposure to workers and members of the public from  $\alpha$  and  $\beta$  surface radioactivity from natural gas well site development drilling operations.
- There is little potential for exceeding public dose limits from external gamma radiation during the drilling phase of natural gas wells.

---

<sup>3</sup> Although the PA TENORM Report was prepared for the Pennsylvania DEP, its findings are equally applicable to the oil and gas industry in West Virginia, as the relevant conditions and operational practices are essentially the same in both states with respect to those matters evaluated by PermaFix Environmental Services, Inc.



- There is little potential for additional Rn exposure to workers and members of the public during the flowback phase of unconventional natural gas wells.
- There is little potential for radiological exposure to workers and members of the public from the handling, hauling, and temporary storage of vertical drill cuttings on natural gas well sites.
- There is little potential for radiological exposure to workers and members of the public from handling, hauling, and temporary storage of horizontal drill cuttings on natural gas well sites.
- There is little potential for radiological exposure to workers and members of the public from hydraulic fracturing proppant sand.
- There is little potential for radiological exposure to workers and members of the public from drilling mud.
- There is little potential for radiological exposure to workers and members of the public from handling and temporary storage of hydraulic fracturing fluid on natural gas well sites.
- There is little potential for radiological exposure to workers and members of the public from handling and temporary storage of flowback fluid on natural gas well sites.
- There is little potential for radiological exposure to workers and members of the public from handling and temporary storage of produced water on natural gas well sites. However, there is a potential for radiological environmental impacts from spills of produced water from unconventional natural gas well sites and from spills that could occur from the transportation and delivery of this fluid.
- There is little potential for additional Rn exposure to workers and members of the public on or near natural gas well sites.

The study does acknowledge the potential for radiological environmental impacts from the spill of flowback and produced water fluids during the flowback, handling and transportation of those fluids, but the study states that these risks are low given environmental requirements applicable to such activities. Furthermore, as discussed above, regulation of environmental impacts from E&P waste, such as produced water, is squarely within the WVDEP's primary jurisdiction to regulate the potential risks to the environment presented by E&P operations.

Additionally, the Marcellus Shale Energy and Environmental Laboratory ("MSEEL") project led by West Virginia University and the Ohio State University in partnership with Northeast Natural Energy, Schlumberger and the National Energy Technology Laboratory of the United States Department of Energy is currently conducting a study of unconventional oil and gas wells in Monongalia County, West Virginia. This study is designed to be the most comprehensive transparent analysis and study of Marcellus wells in the country. It is the first-ever long-term, comprehensive field study of shale gas resources in which scientists will study the process from beginning-to-end. Preliminary findings concerning drill cuttings and completion fluids are consistent with the WVDEP and PADEP Reports.

The Associations are committed to working with the State to develop meaningful and appropriate oversight of TENORM in the oil and gas industry. The Associations are confident that



ongoing studies into TENORM will further support the current findings that there is no threat to human health from TENORM associated with oil and gas operations. Moreover, based on past studies, the Associations believe that the current MSEEL study will only further reinforce the conclusion WVDEP's existing comprehensive framework with respect to the handling of oil and gas waste containing TENORM address the concerns DHHR identifies as the purpose for the Proposed Rule. As such, DHHR should revise the Proposed Rule, consistent with the Associations' attached comments, to ensure it does not engage in the unauthorized duplication of WVDEP's statutory authority to regulate the handling and disposal of oil and gas wastes.

**4. The Proposed Rule's use of risk-based standards should be applied consistently throughout the rule.**

The Associations support DHHR's use of risk-based standards, which serve to protect human health while still providing regulated entities with flexibility in demonstrating compliance. Such risk-based standards should be applied consistently throughout the Proposed Rule, as they are generic to all forms of TENORM. Inconsistencies in the application of risk-based standards within the Proposed Rule could also lead to confusion as to the applicability of Section 16 to TENORM facilities. For example, the exemption described in Section 16.4.f are based on a total effective dose equivalent (TEDE) of 100 mrem/year for a maximally exposed individual. However, in Section 16.5.d, TENORM cannot be released for unrestricted use above 50 mrem/yr. Finally, in section 16.7.c.1, "the average member of the critical group", which is not defined in these rules, may not receive more than 25 mrem/yr TEDE. Proposed standards in this draft rule should be harmonized by applying the risk-based standard of 100 millirem/yr TEDE for a member of the public throughout the rule.

**5. The fiscal note preceding the proposed rule does not comply with the Administrative Procedures Act.**

West Virginia Code § 29A-3-5, incorporating by reference § 29A-3-4(b), requires that a proposed rule "shall have a fiscal note attached itemizing the cost of implementing the rules as they relate to this state and to persons affected by these rules. The fiscal note shall include all information included in a fiscal note for either house of the Legislature and a statement of the economic impact of the rule on the state or its residents." The fiscal note provided by DHHR does not contain sufficient information concerning the cost of implementing the Proposed Rule.

For example, the Proposed Rule may create an unnecessary burden upon the industry by requiring, *inter alia*:

- The cost associated with determining applicability of the risk-based exposure exemption in Section 16.4.f
- Applications for registrations and renewals of registrations
- Inspection of containers
- Labeling of containers
- Sampling and analysis of TENORM waste and monitoring of equipment
- Manifest of shipments



- Radiation protection program, with associated monitoring of radiation levels/exposure
- Reclamation records
- Posting of financial assurance
- Report of TENORM transferred
- Recordkeeping
- Site closure requirements

The Legislature requires an assessment of the financial impact of proposed rules because such rules can, and do, adversely impact the business climate in West Virginia. The Proposed Rule as written could impose duplicative regulatory burdens on the oil and gas industry as well as additional out-of-pocket and administrative costs, with no apparent accompanying reduction in risk to the public. The Proposed Rule will likely adversely affect economic investment in West Virginia and job creation. West Virginia already faces competition for investment in the Marcellus Shale from Pennsylvania and Ohio. Increased regulation in West Virginia may drive investors to budget for development in neighboring states before investing in West Virginia. This can also cause loss of revenues to the state (severance and income—both individual and corporate—taxes), counties (ad valorem taxes) and individuals (royalty income). DHHR should consider these material economic impacts and should include them in the fiscal note for the Proposed Rule. To the extent the DHHR does not intend to incorporate the Associations' attached comments, the Associations respectfully request that DHHR withdraw the Proposed Rule, consult with the oil and gas industry regarding its potential costs, and determine the potential financial impact of the Proposed Rule as required by the West Virginia Code.

6. **The Proposed Rule should clearly exempt wastes from wells drilled pursuant to Well Work Permits issued under Articles 6, 6A, and 21, Chapter 22 of the W. Va. Code to avoid any concerns about conflict with the Legislature's intent to have WVDEP regulate oil and gas activities.**

It might appear that the Proposed Rule is promulgated, at least in part, on the basis of reports that focus on hydraulically fractured horizontal shale wells that involve significantly higher quantities of drill cuttings and waste fluids than conventional wells and coalbed methane ("CBM") wells, but all of these wells are drilled pursuant to permits issued in accordance with Chapter 22, Articles 6, 6A, and 21 of the West Virginia Code. WVDEP OOG—the agency tasked with permitting this activity and the wastes generated from it—requires various documents and information in order to issue a permit under this provision. Specifically, a Fluids/Cuttings Disposal & Reclamation Plan and a Water Management Plan, which specifically discusses the use of recycling produced water across many wells. These regulations, in addition to other requirements imposed by WVDEP's Division of Water & Waste Management, require comprehensive spill prevention and reporting, and importantly, the handling and disposal of oilfield waste.

Even assuming that the Proposed Rule is supported by existing statutory authority, regulating oil and gas and CBM operations within the Proposed Rule is unreasonable and unsupported by scientific evidence. Oil and gas operators have drilled and operated conventional wells in West Virginia for a century, have drilled CBM wells for decades, and have drilled horizontal shale wells for over a decade. The Associations are aware of no example or evidence



of radiation hazards to human health or the environment from those wells. The various scientific studies described above confirm that, at least with respect to the oil and gas industry and E&P wastes in particular, TENORM risks are being adequately addressed through existing WVDEP regulation as described above. In the absence of any evidence to the contrary, the Associations request that at least well work performed in accordance with permits issued under Articles 6, 6A and 21, and the waste streams arising from such wells, be expressly exempt from the Proposed Rule.

**7. The Proposed Rule should be revised to limit incorporation of 64 C.S.R. 23 to provide much needed clarity for the regulated community.**

The Proposed Rule does not appear to identify or otherwise list the applicable requirements of § 64-23-1, *et seq.* The Radiological Health Rules are over 370 pages covering numerous industries, primarily related to health care applications. Various sections of these rules are referenced several times in the Proposed Section 16, without specifying exactly which subparts are applicable to Section 16 regulated activities, such as making a broad reference to § 64-23-6, which itself consists of over 33 pages of detailed requirements. Such broad references unreasonably complicate and burden the persons subject to the Proposed Rule with uncertain compliance obligations. Thus, the Associations request that the Proposed Rule be revised to make references to the specific sections and subparts which are being incorporated by reference.

#### **B. Specific Comments to Proposed Rule**

Attached to these comments is a revised version of Section 16 of the Proposed Rule reflecting substantive and editorial changes requested by the Associations. The requested changes are limited to Section 16 of the Proposed Rule and are highlighted in yellow for ease of reference. The attached redline includes only those pages of the Proposed Rule on which the Associations propose changes. The more significant revisions include:

- **Expand Exemption.** In order to reduce duplicative and overlapping regulation, the § 16.4 exemptions should be expanded to clarify that certain operations are not subject to the Proposed Rule, including activities regulated by: the U.S. Department of Transportation pursuant to the Natural Gas Pipeline Safety Act and Hazardous Liquid Pipeline Safety Act and Rail Safety Improvement Act; the U.S. Environmental Protection Agency pursuant to Subtitle D of the Resource Conservation and Recovery Act ("RCRA"); and WVDEP's OOG, DAP, or DWWM.
- **Add Exemption.** Add an exemption for persons possessing or handling drill cuttings and other drilling waste (e.g. produced water, tank bottoms) arising from or related to well work authorized under Articles 6, 6A and 21 of Chapter 22 of the West Virginia Code.
- **Add Exemption.** Add an exemption for persons handling, transporting, and disposing of produced water under Articles authorized under Article 6A of Chapter 22 of the West Virginia Code.
- **Clarify.** Clarify that oil and gas operators are not considered manufacturers or distributors of TENORM.



- **Clarify.** Clarify that registrations apply to persons or entities for specific activities, facilities and sites and that registration of the TENORM itself is not required.
- **Clarify.** The registration fees need to be more clearly defined for both General and Specific Registrations.
- **General Registration.** Clarify that General Registrations are automatically issued to qualifying entities.
- **Specific Registration.** Clarify that Specific Registration, with regard to manufacturing and distribution, is limited to manufacturers and distributors of any consumer or retail product containing TENORM consistent with Part N of CRPCD recommendations.
- **Revise.** Insert "Naturally Occurring" into the Section 16 title currently shown as "Radiation Safety Requirements for Technologically Enhanced Radioactive Material" for consistency.
- **Revise.** Remove the current financial assurance requirement of \$1,000,000 and allow for site-specific costs to be developed based on actual conditions and activities and clarify that financial assurance is only applicable to specific registrations.

### C. Conclusion

The Associations believe 64 CSR 23, including the revisions contained in the Proposed Rule, is designed to address specific equipment and operations that utilize radiation in some controlled and affirmative manner such as health and industrial contexts. However, the Proposed Rule does not appear to, and should not, apply to oil and gas operations in West Virginia which involve oil and gas waste that may constitute TENORM at some times. Drilling waste is properly and thoroughly regulated by existing state and federal regulations, including through the WVDEP pursuant to RCRA Subtitle D. Moreover, scientific studies demonstrate that there is little potential for impacts to public or workers health. Thus, regulation of oil and gas operations by DHHR as suggested by the Proposed Rule is duplicative, not commensurate with the risk, and, as applied would exceed the DHHR's authority. Therefore, for all of the reasons described in these comments, the Proposed Rule must be revised to avoid conflicting with the express intent of the Legislature on authority to regulate potential environmental and public health risks related to oil and gas industry operations.

The Associations request that DHHR explicitly exempt oil and gas operations regulated by WVDEP from the Proposed Rule and initiate a working relationship with the industry to better understand oil and gas operations and TENORM risks. The Associations have extensive experience in working with other West Virginia agencies on common sense best practices, guidance, rules and regulations to protect residents and the environment. We would look forward to working with DHHR on such a program.



The Associations request that these comments be given serious and careful consideration. We look forward to reviewing the response to comments required pursuant to the West Virginia Administrative Procedures Act.

Respectfully Submitted,

**West Virginia Oil and  
Natural Gas Association**

**Independent Oil and Gas  
Association of West Virginia, Inc.**

Attachment - Section 16 Redlined



ATTACHMENT TO

JOINT COMMENTS OF  
WEST VIRGINIA OIL AND NATURAL GAS ASSOCIATION  
INDEPENDENT OIL AND GAS ASSOCIATION OF WEST VIRGINIA, INC.

TITLE 64  
WEST VIRGINIA LEGISLATIVE RULE  
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

SERIES 23  
RADIOLOGICAL HEALTH RULES

**§64-23-16. Radiation Safety Requirements for Technologically Enhanced Naturally Occurring Radioactive Materials (TENORM).**

16.1. Purpose. ~~This Section establishes radiation protection standards for the possession, use, transfer, and disposal of technologically enhanced naturally occurring radioactive materials (TENORM).~~ -- this section establishes radiation protection standards for Technologically Enhanced Naturally Occurring Radioactive Material (TENORM). These standards include the possession, use, processing, manufacture, distribution, transfer, and disposal of TENORM and of products with TENORM. This section also provides for the licenseregistration of persons and entities possessing, using, processing, manufacturing, distributing, transferring and disposing of TENORM, including licenseregistration termination. The provisions of this section are in addition to the definitions and applicable requirements of all other provisions of this rule.

16.2. Scope.

16.2.a. ~~This rule apply section applies to any person who receives, owns, possesses, uses, processes, transfers, distributes, or disposes of TENORM.~~

16.2.b. ~~The rules in this Part~~This section addresses the introduction of TENORM into products in which neither the TENORM, nor the radiation emitted from the TENORM, is considered to be beneficial to the products.

16.2.c. The manufacture and distribution of products containing TENORM, in which the TENORM or its emitted radiation is considered to be ~~a beneficial attribute to the product~~, are registered under the provisions of section 11 of this rule.

16.2.d. ~~This section does not apply to radionuclides for which NRC retains exclusive jurisdiction.~~ does not apply to source material and byproduct material as both are defined in the Atomic Energy Act of 1954, as amended (AEA 42 USC §2011 et seq.) and relevant regulations implemented by the Nuclear Regulatory Commission (NRC).

16.2.e. Storage incident to transportation and transportation of TENORM are governed by sections 6 and 14 of this rule.

16.3. Definitions. As used in this section, the following definitions apply:



16.3.a. ~~Beneficial Attribute -- the radioactivity of the product necessary to the use of the product.~~

~~16.3.b. Beneficial to the Product -- the TENORM or its emitted radioactivity of is beneficial to the product necessary to the use of the product.~~

~~16.3.b. Critical group - the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.~~

16.3.c. General Environment -- the total terrestrial, atmospheric, and aquatic environments outside the site boundary within which any activity, operation, or process authorized by a general or specific registration issued under this section, is performed.

16.3.d. Institutional Controls: (1) Permanent markers placed at a disposal site, (2) public records and archives, (3) government ownership and rules regarding land or resource use, and (4) other methods of preserving knowledge about the location, design, and contents of a disposal system.

16.3.e. Product -- something produced, made, manufactured, refined, or benefitted by the incorporation of TENORM or its emitted radioactivity, but does not include waste or byproduct material that may include radioactive material.

16.3.f. Reasonably Maximally Exposed Individual -- a representative of a population who is exposed to TENORM at the maximum TENORM concentration measured in environmental media found at a site along with reasonable maximum case exposure assumptions. The exposure is determined by using maximum values for one or more of the most sensitive parameters affecting exposure, based on cautious but reasonable assumptions, while leaving the others at their mean value.

16.3.g. Technologically Enhanced Naturally Occurring Radioactive Material (TENORM) -- naturally-occurring radionuclides whose concentrations are increased by or as a result of past or present human practices. TENORM does not include background radiation or the natural radioactivity of rocks or soils. TENORM does not include uranium or thorium in "source material" as defined in the aca and US NRC regulations. naturally occurring radioactive material in which radionuclide concentrations are increased by or as a result of past or present human practices. TENORM does not include background radiation or the natural radioactivity of rocks or soils. TENORM does not include "source material" and "byproduct material" as both are defined in the Atomic Energy Act of 1954, as amended (AEA 42 USC §2011et seq.) and relevant regulations implemented by the NRC.

16.3.h. Transfer -- ~~the physical relocation of NORM-containing materials not directly associated with commercial distribution within a business's operation or between general or specific registrants. This term does not include a change in legal title to NORM-containing materials that does not involve physical movement of those materials.~~ the physical relocation of TENORM within a business operation or between general or specific ~~licensees~~registrants. This term does not include commercial distribution or a change in legal title to TENORM that does not involve physical movement of those materials.

16.3.i. Total Effective Dose Equivalent (TEDE) -- the sum of the deep dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

#### 16.4. Exemptions.

16.4.a. Persons who receive, own, possess, use, process, transfer, distribute, or dispose of TENORM are exempt from the requirements of this section with respect to any combination of <sup>226</sup>Ra and



<sup>228</sup>Ra if the materials contain, or are contaminated at, concentrations less than 185 becquerel per kilogram (five pCi/gm) excluding natural background. This does not apply to consumer or retail products which are discussed in subsection 16.12.c and section 16.13. Using purposeful dilution to render TENORM waste exempt shall not be allowed without prior agency approval.

16.4.b. Persons who receive products or materials containing TENORM distributed in accordance with a specific registration issued by the agency pursuant to subsection 16.10.a, or to an equivalent registration issued by another licensing state, are exempt from this rule with regard to those products or materials.

~~16.4.c. The distribution, including custom blending, possession, and use of fertilizers containing TENORM, is exempt from the requirements of this Section. Persons who receive, possess, use, process, transfer and distribute, including the preparation of custom blends for distribution, any phosphate or potash ore-based fertilizers containing TENORM are exempt from this section.~~

~~16.4.d. TENORM waste regulated by CERCLA or RCRA (Resources Conservation and Recovery Act) are exempt from this Section. Persons who receive, possess, use, process, transfer, distribute or dispose of TENORM waste regulated by the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA 42 USC §9601 *et seq.* as amended) or by the Resource Conservation and Recovery Act (RCRA 42 USC §6901 *et seq.* as amended), the United States Department of Transportation (49 U.S.C. 101 *et seq.* as amended), including, but not limited to, the Natural Gas Pipeline Safety Act (49 U.S.C. §1671, *et seq.* as amended), the Hazardous Liquid Pipeline Safety Act (49 U.S.C. §601 *et seq.*, as amended), and the Rail Safety Improvement Act, (49 U.S.C. §601 *et seq.* as amended), or by the West Virginia Division of Environmental Protection, including the Division of Air Quality, Division of Water and Waste Management and the Office of Oil and Gas are not subject to this section rule for that TENORM waste.~~

16.4.e. The transportation and storage incident to transportation are governed by Sections 6. and ~~16.4.~~ of this rule.

~~16.4.f. Persons who receive, possess, or use, process, transfer, distribute, or dispose of TENORM shall shall not be subject to the provisions of this section rule when a determination has been made by the agency, based on information provided by persons seeking to qualify for this exemption or otherwise, that the reasonably maximally exposed individual will not receive a public dose with a total effective dose equivalent (TEDE) of more than one millisievert (0.1 rem) in one year from all licensed or registered sources of radiation including TENORM.~~

~~16.4.g. Persons who receive, possess, process, transfer or dispose of drill cuttings or waste containing TENORM arising from or related to well work permits authorized pursuant to articles 6, 6A or 21 of chapter 22 of the West Virginia Code.~~

#### 16.5. Standards for Radiation Protection for TENORM.

16.5.a. No person registered under sections 16.9 and 16.10 shall conduct operations, use, or transfer TENORM in a manner such that a member of the public will receive an annual total effective dose in excess of one millisievert per year (100 mrem/yr.) from all registered sources including TENORM.

16.5.b. Persons subject to a specific registration under this section shall comply with radiation protection standards set out in subsections 6.13, 6.14, 6.15, 6.19, 6.32, 6.33 and 6.59 of section 6 of this rule.



16.5.c. Doses from indoor radon and its progeny shall not be included in total effective dose equivalent calculations. Doses from inhalation of indoor radon and its short half-life (less than one hour) progeny shall not be included in calculations of the TEDE, unless the dose is due to effluent releases from licensed operations involving the handling or processing of TENORM.

16.5.d. No person shall release TENORM for unrestricted use in such a manner that the reasonably maximally exposed individual will receive an annual total effective dose equivalent from the released TENORM in excess of 0.5 millisievert per year (50 mrem/yr.) excluding natural background.

16.6. Protection of Workers During Operations. Each person subject to a specific ~~or general~~ registration under this section shall conduct operations in compliance with the standards for radiation protection set out in the relevant sections 6 and 13 of this rule.

16.7. Release for Unrestricted Use and Conditional Release. Each person subject to a specific registration under this section shall:

16.7.a. Not transfer or release for unrestricted use facilities or equipment contaminated with TENORM in excess of levels in Table 64-23 if;

16.7.b. Not transfer or release for unrestricted use equipment contaminated with TENORM in excess of a surface gamma radiation level of  $\leq 100$  microrems/hour ~~including~~excluding natural background; and

16.7.c. Not transfer land for unrestricted use unless one of the following apply; where the concentration of  $^{226}\text{Ra}$  or  $^{228}\text{Ra}$  in soil averaged over any one hundred (100) square meters exceeds the background level by more than one hundred eighty five (185) Becquerel per kilogram (five [5] pCi/gm); averaged over any fifteen (15) cm layer of soil below the surface, unless compliance with Subsection 16.5.b. through d. can be demonstrated.

16.7.c.1. The average member of the critical group will not receive an annual public dose in excess of 0.25 millisievert (0.025 rem) TEDE from residual radioactive materials on site other than including residual TENORM  $^{226}\text{Ra}$  and  $^{228}\text{Ra}$  and their progeny;

16.7.c.2. The concentration of residual TENORM  $^{226}\text{Ra}$  and  $^{228}\text{Ra}$  on land averaged over 100 square meters, is less than 185 becquerel per kilogram (5 pCi/g) above the background concentration, averaged over the first 15 cm layer of soil, or less than or equal to 15 pCi/g above the background concentrations averaged over subsequent 15 cm layers of soil below the first layer of soil. The 15 cm layers are contiguous depth increments from the surface down. Each of the progeny radionuclides of the residual TENORM  $^{226}\text{Ra}$  and  $^{228}\text{Ra}$  may also be present in concentrations similar to the residual TENORM  $^{226}\text{Ra}$  and  $^{228}\text{Ra}$  concentration; or

16.7.c.3. Where residual TENORM  $^{226}\text{Ra}$  and  $^{228}\text{Ra}$  and their progeny and other residual TENORM radionuclide contamination are present, the sum of fractions shall be used for combining the criteria of subdivisions 16.7.c.1 and 16.7.c.2. The sum of fractions is determined by dividing each average radium concentration by the radium limit of 185 becquerel per kilogram (5 pCi/g) and dividing the estimated annual dose from other residual TENORM radionuclides by 0.25 millisievert (0.025 rem) and then adding the ratios together. The sum of the fractions must be less than, or equal to, one to meet this criterion.

16.7.d. Specific ~~licensees~~registrants shall meet the requirements of sections 16.12. and 16.17 applicable to remediation and termination of the license.



16.7.e. General licensees/registrants shall notify the agency in writing prior to commencing activities to reclaim the site. Decontamination activities require a specific license.

16.7.f. Notification of Site or Area Closure. General licensees/registrants permanently or for a period of two years ceasing the use/possession of radioactive materials at a site or portion of a site or facility, the licensee/registrant shall, within 60 days, provide the following information in writing to the agency:

16.7.f.1. The location of the site or area; and

16.7.f.2. The plan for reclaiming or decontaminating the site or area.

16.7.g. Actions taken to confine TENORM on site or to remediate sites shall be based on expected longevity-related controls for at least 1,000 years.

16.7.h. Conditional release of metal for recycle. Conditionally released metal for recycle shall be allowed only when metal contaminated with TENORM does not exceed a maximum exposure level of 50100 microroentgen per hour, including/excluding background radiation, at any accessible location of the metal surface prior to release from the site.

16.7.i. Equipment not released for unrestricted use. Equipment contaminated with TENORM in excess of levels specified in Table 64-23 li may be transferred pursuant to section 16.22.9.d.

#### 16.8. Disposal and Transfer of Waste for Disposal.

16.8.a. Each person subject to a registration under this rule, unless exempt pursuant to 16.4., shall manage and dispose of wastes containing TENORM:

16.8.a.1. By transfer of the wastes for disposal to a facility ~~registration under~~ subject to the requirements for uranium or thorium byproduct materials in either 40 CFR 192 or 10 CFR 40 Appendix A or to a facility subject to regulation by the West Virginia Department of Environmental Protection; or

16.8.a.2. By transfer of the wastes for disposal to a disposal facility licensed by the US Nuclear Regulatory Commission, an agreement state, or a licensing state; or

16.8.a.3. By transfer of the wastes for disposal at a permitted solid or hazardous waste disposal facility, provided such facility is not prohibited from receiving and disposing such TENORM waste and the disposal is in accordance with applicable federal and state law; or

16.8.a.4. By transfer of the wastes for disposal in another state as otherwise approved by the applicable governmental authority; or

16.8.a.5. By disposal in an injection well approved in accordance with West Virginia Department of Environmental Protection regulations or at an out-of-state injection well approved by the applicable governmental authority

16.8.a.36. In accordance with alternate methods authorized by the agency upon application or upon the agency's initiative, consistent with section 16.5 and where applicable the clean water act, safe drinking water act and other requirements of the US Environmental Protection Agency for disposal of such wastes.

16.8.b. Equipment contaminated with TENORM in excess of levels specified in Table 64-23



~~6e~~, which is to be disposed of as waste, shall be disposed of:

16.8.b.1. So as to prevent any reintroduction into commerce or unrestricted use; and

16.8.b.2. ~~Within disposal areas specifically designed to meet the criteria of Subsection 16.8.a. Equipment contaminated with TENORM not exceeding a maximum exposure level of 100 microroentgen per hour, including excluding background radiation, at any accessible site may be disposed in a landfill that complies with W. Va. Code §22-15-8.~~

~~16.8.c. Transfer of waste containing TENORM for disposal shall be made only to a person specifically authorized by the Nuclear Regulatory Commission, an agreement state or a licensing state, to receive such waste.~~

16.8.d. Records of disposal, including manifests, shall be maintained pursuant to the provisions of section ~~6.38~~ and ~~6.41.f~~ of this rule.

16.8.e. TENORM waste shall not be diluted for the sole purpose of making the waste exempt from the disposal requirements without prior agency approval. The criteria in section 16.5 shall be used by the agency to determine whether to approve such a request.

16.8.f. Drums or shipping containers of TENORM waste transferred offsite for disposal shall not exceed an average concentration of 50.0 picocuries per gram of Radium-226 plus Radium-228, unless the drums or shipping containers containing TENORM are utilized to transfer the TENORM for disposal in another state as approved by an applicable governmental authority; or in accordance with alternate methods authorized by the agency or other applicable state or federal agency.

16.8.g. Containers other than containers regulated pursuant to the West Virginia Aboveground Storage Tank Act, or kept at a facility less than 90 days and having a capacity less than 500 barrels:

16.8.g.1. Containers containing TENORM waste shall be kept in a leak-proof container.

16.8.g.2. The registrant shall use a container made of, or lined with, materials that will not react with, or be incompatible with the TENORM waste to be stored so that the ability of the container to contain the waste is not impaired or compromised.

16.8.g.3. A container containing TENORM waste shall always be closed and sealed during storage or while in transport, except when it is necessary to add or remove waste.

16.8.g.4. A container containing TENORM waste may not be opened, handled, or stored in a manner that may rupture the container or cause it to leak.

16.8.g.5. At least quarterly, the registrant shall inspect areas where containers of TENORM waste are stored, inspecting for leaking or deteriorating containers or containment systems.

16.8.g.6. All containers of TENORM waste shall be stacked in such a manner that each container identification label can be read from the access aisle or area.

16.8.g.7. Each container of TENORM waste shall be labeled with the following information prior to storage:



16.8.-ef.7.A. Name and address of generator;

16.8.-ef.7.B. Type of material (e.g., sludge, scale, dirt, scrap metal, et cetera);

16.8.-ef.7.C. Date stored; and

16.8.-ef.7.D. Labeled as ~~radioactive material~~TENORM waste.

16.8.-ef.8. The registrant shall develop a schedule, not less than quarterly, and procedure for assessing the condition of each container of TENORM waste. The schedule and procedure must be adequate to detect cracks, leaks, corrosion and erosion that may lead to cracks, leaks, or wall thinning to less than the required thickness to maintain vessel/container integrity. Procedures for emptying a waste container to allow entry, procedures for personnel protection, and inspection of the interior must be established when necessary to detect corrosion of the waste container sides and bottom. Records shall be maintained for a period of at least five years.

#### 16.9. General Registration.

16.9.a. Subject to the requirements of sections 16.5 - 16.8 and section 16.10, a general registration ~~is hereby issued~~is hereby issued to persons who shall be required to possess, own, use, transfer, distribute or dispose of TENORM without regard to quantity ~~which registration shall apply to every facility owned or operated by that person.~~

16.9.b. ~~This~~A general registration does not authorize the manufacturing of products containing TENORM in concentrations greater than those specified in section 16.4 nor the receipt and disposal of TENORM wastes from other persons.

16.9.c. The decontamination of equipment, facilities, and land shall be performed only by persons specifically registered by the agency or another licensing state to conduct such work. However, employees or contractors under control and supervision of a general registration can perform routine maintenance on equipment, facilities, and land owned or controlled by the general registration. Maintenance that provides a different pathway for exposure than is found in daily operations and that increases the potential for additional exposure ~~is not considered routine~~must be performed in a manner that ensures exposures do not exceed levels allowable by this section.

16.9.d. Transfer of material or real property.

16.9.d.1. The transfer of TENORM not exempt from this rule from one general registrant to another general registrant is authorized if:

16.9.d.1.A. The equipment and facilities contaminated with TENORM or materials containing TENORM are to be used by the recipient for the same purpose or managed in a similar manner; or

16.9.d.1.B. The transfer of control or ownership of land contaminated with TENORM includes notice to owners of surface and mineral rights to indicate the presence of TENORM.

16.9.d.2. Transfers not made in accordance with subdivision 16.9.d.1 require prior approval by the agency.

16.9.d.3. Transfers made under subdivision 16.9.d.1 do not relieve the general registrant who makes the transfer from the responsibilities of assessing the extent of TENORM contamination or material present, informing the general registrant receiving the TENORM of these assessments, and



maintaining records required by this rule.

16.9.d.4. A general registrant intending to transfer material or real property for unrestricted use shall document compliance with the requirements of section 16.7 of this rule. Records of such compliance shall be kept.

16.9.e. Distribution of TENORM products between general registrants. The distribution of TENORM products not exempt from this rule from one general registration to another general registrant is authorized provided the product is accompanied by labels or manifests or other relevant informational materials which identify the type and amount of TENORM.

16.9.f. The ~~agency Division of Health~~ may, by written notice, require any person authorized by a general registration to apply for and obtain a specific registration. The notice shall state the reason or reasons for requiring a specific registration.

16.10. Specific Registration. Unless otherwise exempt, a person shall obtain a specific registration is required to which shall be applicable to each facility owned or operated by that person in order to:

16.10.a. Manufacture and distribute any TENORM material or consumer or retail product containing TENORM unless authorized by subsection 16.9.e, exempted under the provisions of section 16.4, or registered under the provisions of section 6 of this rule;

16.10.b. Except as provided in subsection 16.9.c, decontaminate equipment or land not otherwise exempted under the provisions of section 16.4 or facilities contaminated with TENORM in excess of the levels set forth in section 16.7, as applicable; for purposes of this section, the term "decontaminate" shall not include maintenance which incidentally results in removal of contamination;

16.10.c. Receive TENORM from other persons for disposal.

16.11. Filing Application for Specific Registration.

16.11.a. Applications for specific registration shall be filed in a manner and on a form prescribed by the agency and include the registration fee as authorized pursuant to 64 CSR 51, Appendix B, Section 3.B.

16.11.b. The agency may at any time after the filing of the original application, and before the expiration of the registration, require further statements in order to enable the agency to determine whether the application should be granted or denied or whether a registration should be modified or revoked.

16.11.c. Each application shall be signed by the applicant or registrant or a person duly authorized to act for and on the registrant's behalf.

16.11.d. An application for a specific registration may include a request for a registration authorizing applicable to one or more facilities, sites and activities.

16.11.e. In an application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the agency provided such references are clear and specific.

16.11.f. Applications and documents submitted to the agency may be made available for public inspection.



16.12. Requirements for the Issuance of Specific Registrations.

16.12.a. A registration application ~~will~~may~~shall~~ be approved if the agency determines that:

16.12.a.1. The applicant is qualified by reason of training and experience to use or manage the TENORM in question for the purpose, or in the manner, requested in accordance with this rule in such a manner as to protect the public health and safety or property;

16.12.a.2. The applicant's proposed equipment, facilities, and procedures are adequate to protect the public health and safety or property;

16.12.a.3. The issuance of the registrant will not be inimical to the health and safety of the public;

16.12.a.4. The applicant satisfied all applicable special requirements in this section; and

16.12.a.5. The applicant has met the financial surety requirements of section 16.23.

16.12.a.6. The applicant has adequately addressed the following items in the application:

16.12.a.6.A. Procedures and equipment for monitoring and protecting workers;

16.12.a.6.B. An evaluation of the radiation levels and concentrations of contamination expected during normal operations;

16.12.a.6.C. Operating and emergency procedures, including procedures for waste reduction and quality assurance of items released for unrestricted use; and

16.12.a.6.D. A method for managing the radioactive material removed from contaminated equipment and facilities.

16.12.b. An application for a specific registration to decontaminate equipment, land, or facilities contaminated with TENORM in excess of the levels set forth in subsections 16.4.a, 16.7.b, or Table 64-23 ~~64-23~~ as applicable, and to dispose of the resulting waste will be approved if:

16.12.b.1. The applicant satisfies the general requirements specified in subsection 16.12.a; and

16.12.b.2. The applicant has adequately addressed the following items in the application:

16.12.b.2.A. Procedures and equipment for monitoring and protection of workers;

16.12.b.2.B. An evaluation of the radiation levels and concentrations of contamination expected during normal operations;

16.12.b.2.C. Operating and emergency procedures, including the identification of contractors expected to be used during emergencies, and procedures for waste reduction and quality assurance of items released for unrestricted use; and

16.12.b.2.D. Method of disposing of the TENORM removed from contaminated equipment, facilities, and land.



16.12.b.2.E. For each site ~~to be listed on the specific registration as an authorized site~~, the applicant shall submit either:

16.12.b.2.E.1. A statement that the applicant owns the site where radioactive material is to be used or stored; or

16.12.b.2.E.2. A statement verifying that the site owner has been informed, in writing, of the use or storage of radioactive material at the site, and that the use of such material is subject to the rules of the Bureau.

16.12.c. An application for a specific ~~license~~registration to transfer materials or manufacture or distribute products containing TENORM to persons exempted from this rule pursuant to subsection 16.4.b will be approved if:

16.12.c.1. The applicant satisfies the general requirements specified in subsection 16.~~22~~12.a;

16.12.c.2. The TENORM is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being; and

16.12.c.3. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the TENORM material or product to demonstrate that the material or product will meet the safety criteria set forth in section 16.13. The information shall include:

16.12.c.3.A. A description of the material or product and its intended use or uses;

16.12.c.3.B. The type, quantity, and concentration of TENORM in each material or product;

16.12.c.3.C. The chemical and physical form of the TENORM in the material or product, and changes in chemical and physical form that may occur during the useful life of the material or product;

16.12.c.3.D. An analysis of the solubility in water and body fluids of the TENORM in the material or product;

16.12.c.3.E. The details of manufacture and design of the material or product relating to containment and shielding of the TENORM and other safety features under normal and severe conditions of handling, storage, use, reuse, and disposal of the material or product;

16.12.c.3.F. The degree of access of human beings to the material or product during normal handling, use, and disposal;

16.12.c.3.G. The total quantity of TENORM expected to be distributed annually in the material or product;

16.12.c.3.H. The expected useful life of the material or product;

16.12.c.3.I. The proposed method of labeling or marking each unit of the material or product with identification of the manufacturer or initial transferor of the product and the radionuclides and quantity of TENORM in the material or product;



16.12.c.3.J. The procedures for prototype testing of the material or product to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, reuse, and disposal;

16.12.c.3.K. The results of the prototype testing of the material or product, including any change in the form of the TENORM contained in it, the extent to which the TENORM may be released to the environment, any change in radiation levels, and any other changes in safety features;

16.12.c.3.L. The estimated external radiation doses and dose commitments relevant to the safety criteria in section 16.13 and the basis for such estimates;

16.12.c.3.M. A determination that the probabilities with respect to doses referred to in section 16.13 meet the safety criteria;

16.12.c.3.N. The quality control procedures to be followed in the production of production lots of the material or product, and the quality control standards the material or product will be required to meet; and

16.12.c.3.O. Any additional information, including experimental studies and tests, required by the agency to facilitate a determination of the radiation safety of the material or product.

16.12.d. Notwithstanding the provisions of subsection 16.13.b, the agency may deny an application for a specific registration if the end uses of the product are frivolous or cannot be reasonably foreseen.

16.13. Safety Criteria for Products. An applicant for a registration under subsection 16.12.c. shall demonstrate that the product is designed and will be manufactured so that:

16.13.a. In normal use and disposal of a single exempt item, and in normal handling and storage of the quantities of exempt items likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, it is unlikely that the TEDE in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will not exceed the doses in Column I of ~~Table 64-23 Hh~~ 16-14.

16.13.b. In use and disposal of a single exempt item and in handling and storage of the quantities of exempt items likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, the probability is low that the containment, shielding, or other safety features of the product would fail under such circumstances that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column II of the Table ~~64-23 Hh~~ in Subsection 16-14, and the probability is negligible that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column III of the Table ~~64-23~~ in Subsection 16-14Hh.

16.13.c. It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the product from wear and abuse likely to occur in normal handling and use of the product during its useful life.

16.14. Table of Organ Doses refer to ~~Table 64-23 Hh~~.

16.15. Issuance of Specific Registrations.

16.15.a. Upon a determination that an application meets the requirements of this rule, the agency ~~will~~may ~~shall~~ issue a specific registration authorizing the proposed activity in such form and containing



such conditions and limitations as it deems appropriate or necessary.

16.15.b. The agency may incorporate in any license-specific registration at the time of issuance, or thereafter by amendment, such additional requirements and conditions with respect to the registrant's receipt, possession, use, and transfer of TENORM subject to this section as it deems appropriate or necessary in order to:

16.15.b.1. Protect public health and safety or property;

16.15.b.2. Require such reports and the keeping of such records, and to provide for such inspections of activities under the license-specific registration as may be appropriate or necessary; and

16.15.b.3. Prevent loss, theft, or loss of control of TENORM subject to this section.

16.16. Conditions of Specific Registration Issued Under Section 16.12.

16.16.a. General Terms and Conditions.

16.16.a.1. Each specific registration issued pursuant to this section shall be subject to all the provisions of this rule, now or hereafter in effect, and to all rules, and orders of the agency.

16.16.a.2. No specific registration issued or granted under this section and no right to possess or utilize TENORM granted by any specific registration issued pursuant to this section shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any specific registration to any person unless the agency shall, after securing full information, find that the transfer is in accordance with the provisions of this rule, and shall give its consent in writing.

16.16.a.3. Each person registered by the agency pursuant to this section shall confine use and possession of the TENORM registered to the locations and purposes authorized in the registration.

16.16.a.4. Each person registered by the agency pursuant to this section is subject to the general license provisions of sections 16.6, 16.7 and 16.8.

16.16.a.5. Each specific registrant shall:

16.16.a.5.A. Notify the agency, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapters of Title II (bankruptcy) of the United States Code (11 U.S.C.) by or against:

16.16.a.5.A.1. A specific registrant;

16.16.a.5.A.2. An entity controlling a specific registrant or listing the specific registration or specific registrant as property of the estate; or

16.16.a.5.A.3. An affiliate of the specific registrant.

16.16.a.5.B. Indicate in their Bankruptcy notification:

16.16.a.5.B.1. The bankruptcy court in which the petition for bankruptcy was filed;  
and

16.16.a.5.B.2. The date of the filing of the petition.



16.16.a.6. Each specific registrant licensee shall notify the agency in writing prior to commencing activities to reclaim the licensed-a listed facility and site.

16.16.a.7. Notification of Site or Area Closure. When a specific registrant-licensee has permanently ceased use of TENORM and all other radioactive materials at a site or portion of a facility and the specific registrant-licensee has not decontaminated the area, or when an area has not been used for a period of two years, the specific registrant-licensee shall, within 60 days, provide the following information in writing to the agency:

16.16.a.7.A. The location of the facility, site, or area;

16.16.a.7.B. The plan for reclaiming or decontaminating the facility, site or area; and

16.16.a.7.C. An evaluation of any changes to the financial assurance submitted in accordance with section 16.23.

16.16.b. Quality Control, Labeling, and Reports of Transfer. Each person registered under subsection 16.12.c shall:

16.16.b.1. Carry out adequate control procedures in the manufacture of the product to assure that each production lot meets the quality control standards approved by the agency;

16.16.b.2. Label or mark each unit so that the manufacturer, processor, producer, or initial transferor of the material or product and the TENORM in the product can be identified; and

16.16.b.3. Maintain records identifying, by name and address, each person to whom TENORM is transferred for use under subsection 16.4.b or the equivalent regulations of a licensing state, and stating the kinds, quantities, and uses of TENORM transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific registration shall be filed with the agency. Each report shall cover the year ending December 31, and shall be filed within 90 days thereafter. If no transfers of TENORM have been made pursuant to subsection 16.12.c during the reporting period, the report shall so indicate.

#### 16.17. Expiration and Termination of Specific Registrations.

16.17.a. Except as provided in subdivision 16.17.d.6 and subsection 16.18.b, each specific registration shall be effective for a term of five years and shall expire at the end of the specified day in the month and year stated therein. Any expiration date on a specific license registration applies only to the authority to engage in licensed designated facilities, sites or activities. Expiration of a specific license registration shall not relieve the licensee registrant of responsibility for decommissioning its facility and terminating the specific license registration.

16.17.b. Each specific registrant shall notify the agency in writing and request termination of the specific registration when the specific registrant decides to terminate all activities involving TENORM authorized under the specific registration. This notification and request for termination of the specific registration must include the reports and information specified in subdivision 16.17.d.6, if applicable. The registrant is subject to the provisions of subsections 16.17.d and 16.17.e, as applicable.

16.17.c. No less than 30 days before the expiration date specified in a specific registration, the registrant shall either:

16.17.c.1. Submit an application for specific registration renewal under section 16.18; or



16.17.c.2. Notify the agency in writing, under subsection 16.17.b, if the specific registrant decides to discontinue all activities involving TENORM.

16.17.d. If a specific registrant does not submit an application for specific registration renewal under Subsection 16.18., the specific registrant shall, on or before the expiration date specified in the specific registration:

16.17.d.1. Terminate use of TENORM;

16.17.d.2. Remove TENORM contamination consistent with the requirements of section 16.7;

16.17.d.3. Properly dispose of TENORM waste; and

16.17.d.4. Submit a report of disposal of TENORM and radiation surveys to confirm the absence of TENORM or to establish the levels of residual TENORM contamination. The specific registrant shall, as appropriate:

16.17.d.4.A. Report levels of radiation in units of micro-roentgens per hour of beta and gamma radiation at one centimeter and gamma radiation at one meter from surfaces and report levels of radioactivity in units of disintegrations per minute (or microcuries) per 100 square centimeters removable and fixed on surfaces, microcuries or Becquerel per milliliter in water, and picocuries or Becquerels per gram in contaminated solids such as soils or concrete; and

16.17.d.4.B. Specify the instruments used and certify that each instrument is properly calibrated and tested.

16.17.d.5. If levels of residual activity are less than those established in section 16.7, the specific registrant shall so certify. If the agency determines that this certification and the information submitted under subdivision 16.17.d.4 is adequate and surveys confirm the findings, the agency will notify the specific registrant in writing that the registration is terminated.

16.17.d.6. If levels of residual TENORM are not in conformance with criteria established in section 16.17, the specific registration continues in effect beyond the expiration date, if necessary, with respect to possession of residual TENORM until the agency notifies the specific registrant in writing that the specific registration is terminated. During this time, the specific registrant is subject to the provisions of subsection 16.17.e. In addition to the information submitted under subdivision ~~17.d.4~~ 16.17.d.4, the specific registrant shall submit a plan, if appropriate, for decontaminating the location or locations and disposing of the residual TENORM.

16.17.e. Each specific registrant who possesses residual TENORM under subdivision 16.17.d.6, following the expiration date specified in the specific registration, shall:

16.17.e.1. Be limited to actions involving TENORM related to preparing the locations for release for unrestricted use; and

16.17.e.2. Continue to control entry to restricted areas until the locations are suitable for release for unrestricted use and the agency notifies the specific registrant in writing that the specific registration is terminated.

16.18. Renewal of Specific Registrations.



16.18.a. Applications for renewal of specific registrations shall be filed in accordance with section 16.11 and section 16.17.c.1.

16.18.b. In any case in which a specific registration, not less than 30 days prior to expiration of an existing specific registration, has filed an application in proper form for renewal or for a new specific registration authorizing the same activities, such existing specific registration shall not expire until final action by the agency.

16.19. Amendment of Specific Registrations at Request of Registrant. Applications for amendment of a specific registration shall be filed in accordance with section 16.11 and shall specify the respects in which the registrant desires the specific registration to be amended and the grounds for such amendment.

16.20. Agency Action on Applications to Renew and Amend Specific Registrations. In considering an application by a specific registrant to renew or amend the specific registration, the agency will apply the criteria set forth in section 16.12.

16.21. Modification and Revocation of Specific Registrations.

~~16.21.a. The terms and conditions of all specific registrations shall be subject to amendment, revision, or modification or the specific registration may be suspended or revoked by reason of amendments to this rule, or by reason of rules, regulations, and orders issued by the agency.~~

16.21.~~ba~~. Any specific registration may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any materially false statement of fact required under provisions of this rule, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the agency to refuse to grant a specific registration on an original application, or for violation of, or failure to observe any of the applicable and substantive terms and conditions of this rule, or of the specific registration, or of any rule, regulation, or order of the agency.

16.21.~~ab~~. Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, the agency shall not modify, suspend or revoke a specific registration prior to the institution of proceedings unless facts or conduct which may warrant such action shall have been called to the attention of the specific registrant in writing and the specific registrant shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

16.22. Reciprocal Recognition of Specific Registrations. Subject to this rule, any person who holds a specific registration or similar specific license from an agreement state or a licensing state, and issued by the agency having jurisdiction where the specific registrant maintains an office for directing the registered activity and at which radiation safety records are normally maintained, is hereby granted a general registration to conduct the activities authorized in such registering document within this state for a period not in excess of 180 days in any calendar year provided that:

16.22.a. The registering document does not limit the activity authorized by such document to specified installations or locations;

16.22.b. The out-of-state registrant or licensee notifies the agency in writing at least three days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the State, and shall be accompanied by a copy of the pertinent registering document. If, for a specific case, the three day period would impose an undue hardship on the out-of-state registrant or licensee, the registrant may, upon application to the agency, obtain permission to proceed sooner. The agency may waive the requirement for filing additional written notifications during



the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general registration provided in subsection 16.22.a;

16.22.c. The out-of-state registrant or licensee complies with all applicable rules of the agency and with all the terms and conditions of the registering document, except any such terms and conditions which may be inconsistent with applicable rules of the agency;

16.22.d. The out-of-state registrant or licensee supplies such other information as the agency may request; and

16.22.e. The out-of-state registrant or licensee shall not transfer or dispose of TENORM possessed or used under the general registration provided in subsection 16.22.a except by transfer to a person:

16.22.e.1. Specifically registered by the agency or by another licensing state to receive such TENORM; or

16.22.e.2. Exempt from the requirements for a registration for such TENORM under section 16.4.

16.23. Financial Surety Arrangements for Specific Registrations. Pursuant to §64 CSR 23, ~~Each specific registrant or applicant for a specific registration under section 16.12 shall post with the agency financial surety, or security, to ensure the protection of the public health and safety and the environment in the event of abandonment, default, or other inability or unwillingness of the specific registrant to meet the requirements of this rule. Financial surety arrangements shall:~~

16.23.a. Consist of cash deposits, certificates of deposit, government securities, irrevocable letters or lines of credit, or any combination of these;

16.23.b. Be in an amount sufficient to meet the applicant's or registrant's obligations ~~under the act and this rule for remediation of the applicable registered facility or facilities, land, and equipment, and shall be a minimum of \$1,000,000.00, unless based upon agency approved cost estimates, an additional amount is necessary for remediation;~~

16.23.c. Be established prior to issuance of the registration or the commencement of operations to assure that sufficient funds will be available to carry out the decontamination and decommissioning of the facility or facilities;

16.23.d. Be continuous for the duration of the registration and for a period coincident with the applicant or registrant responsibility under this rule;

16.23.e. Be available in West Virginia subject to judicial process and execution in the event required for the purposes set forth; and

~~16.23.f. Be established within 90 days of July 1, 2001 for registrations in effect on that date;~~